



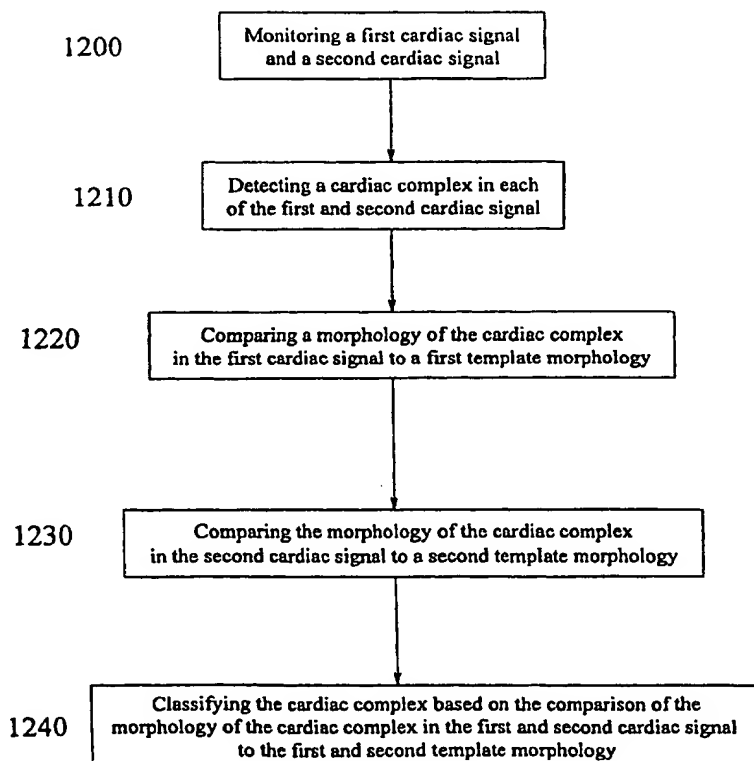
## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>7</sup> : A61N 1/37, 1/362	A1	(11) International Publication Number: <b>WO 00/47278</b> (43) International Publication Date: 17 August 2000 (17.08.00)
(21) International Application Number: PCT/US00/03604 (22) International Filing Date: 11 February 2000 (11.02.00) (30) Priority Data: 09/249,128                      12 February 1999 (12.02.99)                      US (71) Applicant: CARDIAC PACEMAKERS, INC. [US/US]; 4100 Hamline Avenue North, St. Paul, MN 55112 (US). (72) Inventors: HSU, William; 8631 Yalta Street N.E., Circle Pines, MN 55014 (US). SMITH, Joseph, Martin; 6343 Waterman Avenue, St. Louis, MO 63130 (US). (74) Agent: VIKSNINS, Ann, S.; Schwegman, Lundberg, Woessner & Kluth, P.O. Box 2938, Minneapolis, MN 55402 (US).	(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).  <b>Published</b> <i>With international search report.          Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>	

(54) Title: SYSTEM AND METHOD FOR CLASSIFYING CARDIAC COMPLEXES

## (57) Abstract

The present invention provides a system and a method for classifying cardiac complexes based on cardiac information derived from two or more cardiac signals. Two or more cardiac signals containing cardiac complexes are monitored. A cardiac complex in the two or more cardiac signals is isolated in an analysis window. The morphology of the cardiac complex in each of the two or more cardiac signals is then compared to the morphology of a template cardiac complex representing a predetermined cardiac condition. Based on this comparison, the cardiac complex is classified as either belonging or not belonging to the predetermined cardiac condition.



BEST AVAILABLE COPY

**FOR THE PURPOSES OF INFORMATION ONLY**

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

## SYSTEM AND METHOD FOR CLASSIFYING CARDIAC COMPLEXES

**Field of the Invention**

This invention relates generally to the field of medical devices and more particularly to a system and method for classifying sensed cardiac complexes.

5

**Background**

Effective, efficient ventricular pumping action depends on proper cardiac function. Proper cardiac function, in turn, relies on the synchronized contractions of the heart at regular intervals. When normal cardiac rhythm is initiated at the sinoatrial node, the heart is said to be in sinus rhythm. However, 10 when the heart experiences irregularities in its coordinated contraction, due to electrophysiological disturbances caused by a disease process or from an electrical disturbance, the heart is denoted to be arrhythmic. The resulting cardiac arrhythmia impairs cardiac efficiency and can be a potential life threatening event.

15

Cardiac arrhythmias occurring in the atrial of the heart are called supraventricular tachyarrhythmias (SVTs). Cardiac arrhythmias occurring in the ventricular region of the heart are called ventricular tachyarrhythmias (VTs). SVTs and VTs are morphologically and physiologically distinct events. VTs 20 take many forms, including ventricular fibrillation and ventricular tachycardia. Ventricular fibrillation is a condition denoted by extremely rapid, nonsynchronous contractions of the ventricles. This condition is fatal unless the heart is returned to sinus rhythm within a few minutes. Ventricular tachycardia are conditions denoted by a rapid heart beat, 150 to 250 beats per minute, that has its origin in some abnormal location within the ventricular myocardium. The 25 abnormal location is typically results from damage to the ventricular myocardium from a myocardial infarction. Ventricular tachycardia can quickly degenerate into ventricular fibrillation.

SVTs also take many forms, including atrial fibrillation and atrial flutter. Both conditions are characterized by rapid uncoordinated contractions of 30 the atria. Besides being hemodynamically inefficient, the rapid contractions of the atria can also adversely effect the ventricular rate. This occurs when the

aberrant contractile impulse in the atria are transmitted to the ventricles. It is then possible for the aberrant atrial signals to induce VTs, such as a ventricular tachycardia.

Implantable cardioverter/defibrillators (ICDs) have been  
5 established as an effective treatment for patients with serious ventricular tachyarrhythmias. ICDs are able to recognize and treat tachyarrhythmias with a variety of tiered therapies. These tiered therapies range from providing antitachycardia pacing or cardioversion energy for treating tachycardia to defibrillation energy for treating ventricular fibrillation. To effectively deliver  
10 these treatments, the ICD must first identify the what type of tachyrrhythmia is occurring in the heart.

Attempts at identifying tachyarrhythmias have included comparing the morphologies of individual cardiac complexes to model or template cardiac complexes. Template cardiac complex morphologies are  
15 created from cardiac complexes sensed from a signal channel electrogram. Once created, the template cardiac complex morphologies are integrated into morphology algorithms programmed into the ICD. As the ICD encounters a tachycardia episode, cardiac complexes sensed on the single channel electrogram are compared to the template cardiac complex morphologies in the morphology  
20 algorithms. Comparing the morphologies of each cardiac complex to the template cardiac complex requires the signals of the two complexes to be positioned over each other. The morphologies of the signals are then analyzed in a time and energy intensive signal shape analysis to determine whether the cardiac complex should be classified as a template cardiac complex.

25 For the reasons stated above, and for other reasons stated below which will become apparent to those skilled in the art upon reading and understanding the present specification, there is a need in the art for providing a reliable system and method for analyzing and classifying cardiac complexes in a more time and energy efficient manner.

### 30 **Summary of the Invention**

As explained in detail below, the present subject matter utilizes cardiac information from two or more cardiac signals to analyze and classify sensed cardiac complexes in a more time and energy efficient manner. The two



or more cardiac signals are sensed from two or more locations within, or on, the heart of the patient. A cardiac complex sensed using two or more cardiac signals includes the relative time at which the cardiac complex is sensed in each of the two or more cardiac signals. This additional factor allows for a more efficient  
5 comparison to be made between a sensed cardiac complex and a template cardiac complex representing a predetermined cardiac condition. Based on the comparison, the cardiac complex is classified and this information is used to either determine what type of therapy to deliver to a patient or to assess the occurrence of a variety of predetermined cardiac conditions which may be  
10 helpful in providing treatment to the patient.

In one embodiment, the present subject matter provides for the monitoring of two or more cardiac signals representative of a patient's cardiac activity. A cardiac complex is detected in each of the two or more cardiac signals, where the cardiac complex in each of the two or more cardiac signals  
15 represents at least a portion of the heart's cardiac cycle. The morphology of the cardiac complex in each of the two or more cardiac signals is then compared to the morphology of a template cardiac complex. Based on the morphology comparison, the cardiac complex is then classified as either being associated with the template cardiac complex or not being associated with the template  
20 cardiac complex.

In one embodiment, a first signal and a second signal representative of electrical cardiac activity are monitored. As the first signal is being monitored it is analyzed to detect the onset of a tachycardia episode. When a tachycardia episode is detected, individual cardiac complexes in the first  
25 signal and the second signal are detected and windowed for analysis. Predetermined features are then located in the cardiac complex detected in the first signal and in a first normal sinus rhythm representative complex. In one embodiment, the predetermined features include repeatably identifiable complex sections common to the cardiac complex detected in the first signal and the first  
30 NSR representative complex.

The predetermined features located in the first signal and in the first NSR representative complex are then aligned within the analysis window. The cardiac complex detected in the second signal is then compared to a second

NSR representative complex to determine whether the cardiac complex is an arrhythmic cardiac complex. In one embodiment, the morphology of the second NSR representative complex and the morphology of the cardiac complex detected in the second signal to determine whether the cardiac complex is an  
5 arrhythmic complex.

In an alternative embodiment, as a cardiac complexes are detected in the first signal and the second signal they are windowed for analysis. Predetermined features are then located in the cardiac complex detected in the first signal and in a first normal sinus rhythm representative complex. Scalar  
10 values are then generated as a function of the position, or location, of the predetermined features in each of the cardiac signals. The scalar values are then used to create a cardiac vector which represents the cardiac complex.

The cardiac vector is compared to one or more classification vectors, where each of the one or more classification vectors represents a  
15 predetermined cardiac condition. A similarity coefficient is determined for the comparison between the cardiac vector and each of the one or more classification vectors. When a similarity coefficient for the comparison of the cardiac vector and a classification vector exceeds a predetermined threshold, the cardiac complex is classified as the predetermined cardiac condition represented by the  
20 classification vector.

Additionally, the cardiac vector can be aligned with a classification vector prior to comparing the two vectors. In one embodiment, the process of aligning includes adjusting each scalar value in the cardiac vector so one of the element positions of the cardiac vector equals a scalar value in a  
25 corresponding element position in a classification vector.

In an alternative embodiment, as a cardiac complexes are detected in the first signal and the second signal they are windowed for analysis. The morphology of the cardiac complex in the first cardiac signal and the second cardiac signal is then compared to a first template morphology and a second  
30 template morphology, respectively. The cardiac complex is then classified based on the comparison of the morphology of the cardiac complex in the first cardiac signal and the second cardiac signal to the first template morphology and the second template morphology.

These and other features and advantages of the invention will become apparent from the following description of the embodiments of the invention.

### **Brief Description of the Drawings**

Figure 1 is an embodiment of a cardiac complex sensed in two or more  
5 cardiac signals according to the present subject matter;

Figure 2 is an embodiment of cardiac vectors plotted on a three-dimensional Cartesian coordinate system;

Figure 3 is a flow diagram illustrating one embodiment of the present subject matter;

10 Figure 4 is an embodiment of a cardiac complex sensed in two or more cardiac signals according to the present subject matter;

Figure 5 is a schematic view of one embodiment of an implantable medical device with an endocardial lead implanted in a heart from which segments have been removed to show details;

15 Figure 6 is a block diagram of an implantable medical device according to one embodiment of the present subject matter;

Figure 7 is a flow diagram illustrating one embodiment of the present subject matter;

20 Figure 8 is one embodiment of aligning cardiac complexes according to the present subject matter;

Figure 9 is one embodiment of aligning cardiac complexes according to the present subject matter;

Figure 10 is a flow diagram illustrating one embodiment of the present subject matter;

25 Figure 11 is a flow diagram illustrating one embodiment of the present subject matter; and

Figure 12 is a flow diagram illustrating one embodiment of the present subject matter.

### **Detailed Description**

30 In the following detailed description, reference is made to the accompanying drawings which form a part hereof and in which is shown by way of illustration specific embodiments in which the invention may be practiced. These embodiments are described in sufficient detail to enable those skilled in

the art to practice and use the invention, and it is to be understood that other embodiments may be utilized and that electrical, logical, and structural changes may be made without departing from the spirit and scope of the present invention. The following detailed description is, therefore, not to be taken in a limiting sense and the scope of the present invention is defined by the appended claims and their equivalents.

The embodiments of the present subject matter illustrated herein are described as being included in an implantable cardiac defibrillator, which may include numerous pacing modes known in the art and an external medical device programmer. In one embodiment, the implantable cardiac defibrillator is a single chamber defibrillator. In an alternative embodiment, the implantable cardiac defibrillator is a dual chamber defibrillator. Examples of both single and dual chamber implantable cardiac defibrillators are known in the art. However, the present medical system can also be implemented in an external cardioverter/monitor system as are known in the art. Also, the present medical system can also be implemented in an implantable atrial cardioverter-defibrillator, which may include numerous pacing modes known in the art. Furthermore, although the present system is described in conjunction with an implantable cardiac defibrillator having a microprocessor based architecture, it will be understood that the implantable cardiac defibrillator (or other implanted device) may be implemented in any logic based custom integrated circuit architecture, if desired.

With respect to the present subject matter, accurate classification of sensed cardiac complexes is important to an overall diagnosis and treatment of a patient's cardiac condition. In an effort to classify and categorize sensed cardiac complexes, the morphology of individual cardiac complexes is compared to template cardiac complexes. The template cardiac complexes are derived from cardiac complexes sensed during arrhythmic or non-arrhythmic cardiac episodes.

The cardiac signals used in creating the template cardiac complex and classifying sensed cardiac complexes have typically been detected using a signal channel electrogram. Single channel electrograms, however, limit the amount of cardiac information available to use in classifying cardiac complexes. In contrast, one unique aspect of the present subject matter is that cardiac

information from two or more cardiac channels is used to classify sensed cardiac complexes. Using two or more cardiac channels provides cardiac information from two or more locations within, or on, the heart of the patient. By utilizing multiple cardiac channels, cardiac information (e.g., sensed cardiac complexes) from the two or more cardiac regions and/or locations provide a larger overall and more complete "view" of the sensed cardiac complexes.

The present subject matter uses two or more electrogram channels in a process of analyzing and classifying cardiac complexes. Each electrogram channel is used to sense a cardiac signal, where the cardiac signal includes cardiac complexes representative of at least a portion of a cardiac cycle. By way of example, and not by way of limitation, portions of the cardiac cycle sensed can include, but are not limited to, P-waves, QRS-cardiac complexes, and R-waves. Other portions of the cardiac cycle, including sensed signals of the entire cardiac complex are considered useful and within the scope of the present subject matter.

In one embodiment, the present subject matter provides for two or more electrogram channels to simultaneously record cardiac complexes as they occur in the heart. As the cardiac complexes occur, each electrogram channel detects cardiac complexes representing portions of the cardiac cycle. The two or more electrogram channels are being sensed from sensors in or on different cardiac locations. While sensors may detect the electrical activity during the same portion of the cardiac cycle, having the sensors in different cardiac locations allows for cardiac information about the same cardiac complex to be gathered from a different "view" of the cardiac cycle. Each cardiac complex sensed with the two or more electrogram channels is placed in an analysis window, where the cardiac complex is isolated for analysis. In one embodiment, each cardiac complex is windowed by isolating and plotting the portions of the simultaneously sensed cardiac complex in the two or more electrogram channels as they occurred in time.

Figure 1 shows one embodiment of a windowed cardiac complex 100. In the present example, the windowed cardiac complex 100 has a first cardiac channel 104, a second cardiac channel 108 and a third cardiac channel 112. Cardiac complexes are sensed over the first cardiac channel 104, the

second cardiac channel 108 and the third cardiac channel 112, where each cardiac channel may sense a different portion of the cardiac complex (*e.g.*, R-wave, QRS-cardiac complex, P-wave, etc.). In the present example, the windowed cardiac complex 100 has three views of a cardiac complex as sensed  
5 over the three cardiac channels. A first cardiac complex 116 is shown in cardiac signal sensed in the first cardiac channel 104. A second cardiac complex 120 is shown in cardiac signal sensed in the second cardiac channel 108. Finally, a third cardiac complex 123 is shown in cardiac signal sensed in the third cardiac channel 112. The first, second and third cardiac complex 116, 120 and 124 are  
10 representative of at least a portion of a single cardiac cycle. In one embodiment, the first, second and third cardiac complex 116, 120 and 124 are snapshots of the single cardiac cycle taken either at different locations within or on the heart and/or taken using different electrode configurations (*e.g.*, far-field, near-field).

Cardiac information is derived from the windowed cardiac  
15 complexes. In one embodiment, information derived from the windowed cardiac complexes includes values derived or taken from one or more predetermined features on the cardiac complex sensed in each of the two or more cardiac channels. By way of example, and not by limitation, predetermined features of the cardiac complexes that are useful in deriving information include a  
20 maximum deflection of the cardiac complex, a beginning of a cardiac complex as indicated by a predetermined deviation of the cardiac signal from a baseline signal, an ending of a cardiac complex as indicated by a return of the first cardiac signal to a baseline signal and a fiducial point (the point of greatest slope along the cardiac complex signal). Other features of the cardiac complex signal are  
25 also useful for deriving information. In one embodiment, the selection criteria for these additional features of a cardiac complex is that the feature be a repeatably identifiable portion of the cardiac complex. In one embodiment, the features are selectively programmed into the medical device system.

Figure 1 shows several examples of predetermined features of the  
30 sensed cardiac complex that are useful in deriving information. In one embodiment, a beginning of the first, second and third cardiac complex (116, 120 and 124) sensed in the first, second and third cardiac channel (104, 108 and 112), respectively, is generally shown at 128. A maximum deflection point of

the first, second and third cardiac complex (116, 120 and 124) is shown generally at 132. Finally, an ending point of the first, second and third cardiac complex (116, 120 and 124) is shown generally at 136.

In one embodiment, the cardiac complexes sensed in the two or  
5 more cardiac channels are windowed with each of the signals of the cardiac complexes represented as a voltage at a function of time. Figure 1 shows an example of the first, second and third cardiac complex (116, 120 and 124) sensed in the first, second and third cardiac channel (104, 108 and 112) being plotted as voltage as a function of time. Once the cardiac complex sensed in the two or  
10 more cardiac channels is represented in this fashion, information can be derived from the specific features of the cardiac complexes.

In one embodiment, the information derived from the cardiac complexes in each of the cardiac channels is the time the repeatably identifiable feature of the cardiac complex occurred. Alternatively, the information derived  
15 is a time difference between pairs of repeatably identifiable features on a cardiac complex sensed in one of the two or more electrogram channels. In one embodiment, a first time difference 140 is between the beginning 128 of the first cardiac complex 116 and the end 136 of the first cardiac complex. In an additional embodiment, the information derived is a time difference between  
20 pairs of repeatably identifiable features on two different cardiac complexes sensed in two electrogram channels. In a further embodiment, the information derived is a combination of the time difference between pairs of repeatably identifiable features on two different cardiac complexes sensed in two  
25 electrogram channels and the time differences from pairs of repeatably identifiable features on a cardiac complex sensed in one of the two or more electrogram channels.

Information from multiple cardiac channels can then be used to represent the cardiac complex. In one embodiment, the cardiac complex sensed in multiple cardiac channels can be numerically represented. One way of  
30 numerically representing the cardiac complex is to use scalar values derived from the cardiac signals of the cardiac complex. In one embodiment, the scalar values derived from the cardiac signals of the cardiac complex are the times repeatably identifiable features of the cardiac complex occur. Alternatively, time

differences between the repeatably identifiable features, as previously described, are used to derive the scalar values. In an additional embodiment, the scalar values can be derived from a magnitude of the position of the predetermined feature for each of the two or more cardiac signals. In one embodiment, the  
5 magnitude of the position of the predetermined feature is the voltage measurement of the maximum deflection position along the cardiac signal.

The values derived for a cardiac complex are then used to create an "N" dimensional cardiac complex vector. In one embodiment, the cardiac complex vector has the form:  $A = [A_1, A_2, A_3, \dots A_n]$ , where each of the  
10 values  $A_1 - A_n$  represent scalar values derived from the repeatably identifiable features of the cardiac complex. The cardiac complex vector represents the cardiac complex, and is used to identify and classify the cardiac complex.

Once the cardiac complex vector has been derived from cardiac complex information taken from the two or more cardiac channels, the cardiac  
15 complex vector is compared to one or more classification vectors. In one embodiment, a classification vector represent a typical cardiac complex of a specific cardiac arrhythmia or cardiac state. For example, a classification vector can represent a ventricular tachycardia (VT) complex, where there can be one or more classification vectors to represent one or more different manifestations of  
20 ventricular tachycardia complexes. Additionally, classification vectors can represent supraventricular tachycardia (SVT) complexes, premature ventricular contraction (PVC) complexes, complexes indicating ischemic events, and any predefined representation of a cardiac complex.

In one embodiment, classification vectors are predefined  
25 classification vectors derived from cardiac complexes sensed over two or more cardiac channels for a population of patients. In one embodiment, the population of patients chosen to determine a classification vector display or manifest the cardiac condition of interest (e.g., VT, SVT, PVC). Cardiac complexes of the cardiac conditions of interest are recorded over two or more cardiac channels  
30 from the patients. Using repeatably identifiable features of the multiple cardiac signals representing each cardiac complex, classification vectors for a cardiac condition are developed. In one embodiment, cardiac complexes are sensed and recorded during Holter monitoring.



In one embodiment, the classification vectors has the form:  $C = [C1, C2, C3, \dots Cn]$ , where each of the values  $C1 - Cn$  represent scalar values derived from the repeatably identifiable features of the cardiac complexes. In one embodiment, each of the values  $C1 - Cn$  are average values derived from  
5 repeatably identifiable features of the cardiac complexes for the patient population. In an alternative embodiment, each of the values  $C1 - Cn$  are median values derived from repeatably identifiable features of the cardiac complexes for the patient population. One or more of the predetermined classification vectors can then be used in the implantable medical device to classify sensed cardiac  
10 complexes.

In an alternative embodiment, the classification vectors are derived from cardiac complexes sensed from the patient. In one embodiment, two or more cardiac signals are recorded from the patient for a predetermined length of time. In one embodiment, sensing and recording the cardiac complexes is  
15 accomplished through Holter monitoring. From the recorded cardiac complexes, classification vectors are developed as previously discussed. In an additional embodiment, classification vectors represent predefined deviations between two or more repeatably identifiable features of a cardiac complex in the two or more cardiac signals. In this embodiment, the classification vector is not representing  
20 a particular cardiac condition (e.g., VT, SVT, PVC complex) but rather is representative of a very specific cardiac condition or occurrence that the physician want to pay particular attention to. By developing and programming this type of classification vector, the physician can determine how may cardiac complexes of this particular type are occurring.

25 In an alternative embodiment, classification vectors are created after the medical device system has been implanted into the patient. One way to create patient specific classification vectors is to derive scalar values from predetermined features of the cardiac complexes sensed in the two or more cardiac channels. As the scalar values are determined from the first sensed  
30 cardiac complex, the medical device system determines the cardiac complex vector. The cardiac complex vector for the first cardiac complex is then classified as a first class of sensed cardiac complexes. As the second cardiac complex is sensed, the medical device system determines the cardiac complex

vector A for the second cardiac complex. The cardiac complex vector A for the second cardiac complex is then compared to the cardiac complex vector A for the first cardiac complex to determine whether the second cardiac complex should be classified in the first class of sensed cardiac complexes or classified in  
 5 a second class of sensed cardiac complexes.

In one embodiment, determining whether a cardiac complex should be grouped with one or more classified cardiac complexes is accomplished through a process of comparing the complex vector A of the cardiac complex to be classified with the complex vector A of the cardiac complex that founded the  
 10 class of cardiac complexes. Figure 2 shows an embodiment of cardiac complex classes. Figure 2 shows cardiac complexes being plotted in a Cartesian coordinate system with three-dimensions 200. Cardiac vectors plotted in 200 have three values  $A=[A_1, A_2, A_3]$ . As the first cardiac complex of a patient is sensed, the cardiac vector is determined. As previously discussed, the first  
 15 cardiac complex becomes the first class of sensed cardiac complexes. The cardiac vector of the first cardiac complex is shown at 204.

The cardiac vector of the first cardiac complex not only establishes the first class of sensed cardiac complexes, but it is also used to determined whether subsequently sensed cardiac complexes should be included in the first  
 20 class of sensed cardiac complexes or excluded to join another class of sensed cardiac complex or form a new class of sensed cardiac complexes. In one embodiment, to determine whether a second cardiac complex is classified with the first class of sensed cardiac complexes the cardiac vector of the second cardiac complex is compared to the cardiac vector of the first cardiac complex.

25 In one embodiment, a mean square error calculation is used to determine if the scalar values of the cardiac vectors are sufficiently close, or within a region, or "neighborhood" to classify the second cardiac complex in the first class of cardiac complexes. In one embodiment, the mean square error is represented as  $\sum (A_{i(n \text{ class})} - A_i)^2 \leq T$ , where  $A_{i(n \text{ class})}$  represents the  $i$ th scalar  
 30 value ( $A_1, A_2, A_3$ ) of the  $n$  class (first class, second class, third class, ...,  $n$ th class) of sensed cardiac complexes and  $T$  is a predetermined threshold value. In one embodiment, the predetermined threshold value  $T$  defines the region around the cardiac complex representing each of the classes of sensed cardiac complexes.

Figure 2 shows one example of a first region 208 surrounding the cardiac vector of the first cardiac complex 204. As previously discussed, after the second cardiac complex is sensed, the cardiac vector representing the second cardiac complex is compared to the cardiac vector representing the first class of cardiac complexes, which in this case is the first cardiac complex 204. In one embodiment, if the cardiac vector representing the second cardiac complex falls on or within the first region 208, the second cardiac complex is classified as part of the first class of cardiac complexes.

In an alternative embodiment, if the cardiac vector representing the second cardiac complex falls outside the first region 208, the second cardiac complex is used to create a second class of cardiac complexes. In one embodiment, the cardiac vector of the second cardiac complex is shown at 212. A second region 216 surrounds the second cardiac complex 212. As previously discussed, the size of the second region 216 surrounding the second cardiac complex is dependent on the predetermined threshold value T.

As a subsequent cardiac complex is sensed a cardiac vector representing the cardiac complex is determined. The cardiac vector is then compared to each established class of cardiac complex. If the cardiac vector is found to fall within the region around a cardiac vector representing a class of cardiac complexes, the cardiac vector is classified with that class of cardiac complexes. So, if the cardiac complex is found to fall into the region representing a third class of cardiac complexes, the cardiac complex would be classified and counted with the third class of cardiac complexes. If, however, the cardiac complex does not fall into a region surrounding one or more classes of cardiac complexes, the cardiac vector of the cardiac complex is used to create a new class (an "nth" cardiac class) of cardiac complexes.

The cardiac vectors that establish a class of cardiac complexes are electronically stored in the implantable medical device. In addition to electronically storing the cardiac vectors, the medical device system also stores at least the electrocardiogram signal of the cardiac complex that established the class of cardiac complexes. In an additional embodiment, values for the cardiac vectors classified in each of the classes of cardiac complexes are also electronically stored in the medical device system. In one embodiment, it is

possible that a cardiac complex is classified into two or more classes of cardiac complexes. In one embodiment, the cardiac complex falling into two or more classes of cardiac complexes will be reported in each class of cardiac complexes. In an alternative embodiment, cardiac complexes falling into two or more classes  
5 will classified and reported in the class that they were originally classified.

The patient cardiac complexes are sensed and classified by the implantable medical device for a predetermined period of time. In one embodiment, the predetermined period of time over which cardiac complexes are sensed and used to create the classes of cardiac complexes is programmed by the  
10 patient's attending physician. In one embodiment, cardiac complexes are sensed over a continuous period of time. Alternatively, the implantable medical device is programmed to classify sense cardiac complexes during predetermined time segments over the course of 24 hours. Additionally, the implantable medical device is programmed to classify sense cardiac complexes only after the cardiac  
15 rate (ventricular and/or atrial rate) has reached or exceeded are predetermined threshold (e.g., known cardiac rate threshold indicative of ventricular tachycardia, atrial tachycardia, etc.).

Upon a follow-up visit to the patient's physician, the cardiac information contained in the implantable medical device is down-loaded to a  
20 medical device programmer unit. In one embodiment, information relating to cardiac complexes used to establish classes of cardiac complexes is down-loaded and displayed on a display screen of the medical device programmer. Additionally, the number of cardiac complexes classified into each of the classes of cardiac complexes can be displayed. Electrocardiogram signals representative  
25 of each class of cardiac complex can also be displayed. The physician then uses the classes of cardiac complexes to define or designate classification vectors which are subsequently used to identify cardiac complexes and classify a cardiac arrhythmia that the patient may experience.

Figure 3 shows one embodiment of a method of the present subject  
30 matter. At 300, two or more cardiac signals representative of electrical cardiac activity are monitored. The cardiac signals are monitored to detect cardiac complexes occurring in the two or more cardiac signals. In one embodiment, an implantable medical device, such as an implantable cardioverter defibrillator, is

used to detect cardiac complexes in the two or more cardiac signals. In one embodiment, the implantable medical device has two or more cardiac electrodes which allow for near-field and/or far-field cardiac signals to be sensed from a heart.

5                   At 310, the cardiac complex present in the two or more cardiac signals is isolated in an analysis window (or "windowed" for analysis). As previously discussed, windowing isolates a section, or portion, of the two or more cardiac signals which each contain a view of the cardiac complex that is being classified. After the cardiac signals containing the cardiac complex have  
10                   been isolated, at least one predetermined feature is located in the cardiac complex present in each of the two or more cardiac signals.

                  Once the cardiac signals containing the cardiac complex have been windowed, scalar values from predetermined features of the cardiac complex are generated. In one embodiment, the scalar values are generated as a function of  
15                   the position of the predetermined feature, or features, on each of the two or more cardiac signals. The scalar values are then used to create a cardiac vector, where the cardiac vector represents the cardiac complex.

                  Figure 4 shows one embodiment of cardiac complexes of a cardiac cycle windowed for analysis and classification. A first cardiac complex 400 is  
20                   present in the first cardiac signal 404 and a second cardiac complex 408 is present in a second cardiac signal 412. As previously discussed, the two or more cardiac signals are sensed simultaneously from the heart, and so the first cardiac complex 400 and the second cardiac complex 408 are representative of portions of a complete cardiac cycle occurring in the heart.

25                   Predetermined features of the cardiac complex in each cardiac signal are used to derive a cardiac vector. In the present example, the cardiac vector is programmed to have four values, such that  $A=[A1, A2, A3, A4]$ . Each of the values A1 - A4 represent scalar values derived from the repeatably identifiable features of the cardiac complex. In one embodiment, A1 is  
30                   programmed to be the beginning time 416 of the first cardiac complex 400, A2 is programmed to be the time of the maximum deflection point 420 of the first cardiac complex 400, A3 is programmed to be the time difference 424 between the time of the maximum deflection point 420 and the time of the maximum

deflection point 428 of the second cardiac complex 408, and A4 is programmed to be the beginning time 432 of the second cardiac complex 408.

Referring again to Figure 3, after a cardiac vector has been determined for the cardiac complex, the cardiac vector is compared to one or more classification vectors at 330. In one embodiment, the one or more classification vectors represents a predetermined cardiac condition. For example, the predetermined cardiac conditions can include, but are not limited to, ventricular and supraventricular tachycardia, PVCs, ischemia, or other predetermined cardiac conditions designated by a physician. In addition, the cardiac vector has the same vector dimension as the classification vectors. In one embodiment, the scalar values making up the cardiac vector are determined from the same relative predetermined features of the cardiac signals sensed in the same general cardiac location using the same general cardiac electrode configuration.

In one embodiment, the cardiac vector is compared to the classification vectors to determine whether the cardiac vector similar enough to one or more classification vectors to classify the cardiac complex. In one embodiment, a similarity coefficient is determined from each comparison of the cardiac vector and the one or more classification vectors. Based on this similarity coefficient, the cardiac complex is classified as the predetermined cardiac condition when the cardiac complex similarity coefficient exceed a predetermined threshold. In one embodiment, a mean square error is used to determine the similarity coefficient. In one embodiment, the mean square error value is represented as  $\sum (A_i - C_i)^2 \leq X$ , where  $A_i$  represents the  $i$ th scalar value ( $A_1 - A_n$ ) of the cardiac vector,  $C_i$  represents the  $i$ th scalar value ( $C_1 - C_n$ ) of the classification vector and  $X$  is a predetermined threshold value. In one embodiment, the predetermined threshold value  $X$  defines the region or a neighborhood around the classification vector which is deemed to be sufficiently close to permit classifying the cardiac complex represented by the cardiac vector as a general class of cardiac complexes represented by the classification vector. Based on the comparison, the cardiac complex is classified at 340 as being a member of the group represented by one or more classification vectors if possible.

In an additional embodiment, prior to comparing the cardiac vector to the classification vectors, the cardiac vector is aligned, or coordinated with, each of the classification vectors. In one embodiment, the cardiac vector and the classification vectors include element positions (A1 and C1 are in the first element position, A2 and C2 are in the second element position, etc.) which are occupied by the scalar values. The cardiac vector and a classification vector are aligned around the scalar values in the same element position (i.e., a coordinating element position) in both the cardiac vector and the classification vector.

In one embodiment, the process of aligning the cardiac vector and the classification vector involves adjusting each scalar value of the cardiac vector so one of the element positions of the cardiac vector equals a scalar value in a corresponding element position in a classification vector. So, when the scalar values in the vectors are the time of occurrence of features in different channels, the vectors are aligned by add or subtract an appropriate numerical value to all the elements of the cardiac vector (e.g., the scalar values in the cardiac vector) so that the scalar value in the coordinating element position of the cardiac vector has the same numerical value as the coordinating element position of the classification vector.

In one embodiment of aligning a cardiac vector and a classification vector, a cardiac complex is sensed two or more cardiac channels, from which a cardiac vector  $A=[A1, A2, A3, A4]$  is determined. In this embodiment, the elements of the vector are times at which the repeatably identifiable features of the cardiac complex occurred in the two or more cardiac channels. One or more classification vectors are provided having the general form  $C=[C1, C2, C3, C4]$ . In one embodiment, the cardiac vector is aligned, or coordinated, around the same element position (the coordinating element) with each classification vector the cardiac vector is compared with. In one embodiment, the coordinating element is the first position in the cardiac vector and the classifying vector, A1 and C1. A numerical value Y is added to, or subtracted from, the value of A1 so that A1 equals C1. So,  $A1 + Y = C1$ , where Y can have either a positive or a negative numerical value. In addition to modifying the value of A1 with Y, Y is also added to the remaining elements of the cardiac vector. So, a cardiac vector

aligned with a classification vector has the form  $A_a = [A1+Y, A2+Y, A3+Y, A4+Y]$ , where  $A1+Y = C1$  of the classification vector  $C = [C1, C2, C3, C4]$ . After the cardiac vector has been aligned with the classification vector, the elements of the vectors, excluding the coordinating elements, are compared.

- 5 This means that for the present example, the classification vector  $A_a = [A2+Y, A3+Y, A4+Y]$  would be compared to the classification vector  $C = [C2, C3, C4]$ . Finally, the cardiac vector can be aligned with a classification vector around any element (e.g.,  $A1/C1, A2/C2$ , etc.) in the pair of vectors.

- As previously discussed, the present subject matter uses two or  
10 more electrogram channels in a process of analyzing and classifying cardiac complexes. In one embodiment, a first cardiac signal and a second cardiac signal are sensed over a first electrogram channel and a second electrogram channel, respectively. During a tachycardia episode, a cardiac complex is detected in the first cardiac signal and the second cardiac signal. The morphology of the first  
15 cardiac signal and the second cardiac signal representing the cardiac complex can then be compared to template cardiac complexes. Based on this comparison, the cardiac complex can be classified as being representative of one or more predetermined cardiac rhythm states. Predetermined cardiac rhythm states can include, but are not limited to, arrhythmic or non-arrhythmic, normal sinus  
20 rhythm (NSR), ventricular tachycardia and/or supraventricular tachycardia cardiac rhythm states.

- In an additional embodiment, the process of comparing the morphology of the cardiac complex to a template cardiac complex includes the act of aligning, or coordinating, the cardiac complex sensed in a first cardiac  
25 signal of the two or more cardiac signals with a template cardiac complex having been derived from cardiac complexes sensed in the first cardiac signal. Alternatively, the morphology of the cardiac complex sensed in the two or more cardiac channels is compared to the morphology of the template cardiac complex which was derived from cardiac complexes sensed in the two or more cardiac  
30 channels.

In one embodiment, a first cardiac signal and a second cardiac signal are sensed over a first electrogram channel and a second electrogram channel, respectively. During a tachycardia episode, a cardiac complex is



detected in the first cardiac signal and the second cardiac signal. In one embodiment, the cardiac complex detected in the first cardiac signal is aligned, or coordinated, with a first normal sinus rhythm (NSR) representative complex. In one embodiment, the first NSR representative complex is the template cardiac  
5 complex which, in the present embodiment, was derived from normal sinus rhythm cardiac complexes detected in the first cardiac signal.

Once the cardiac complex from the first cardiac signal has been aligned with the first NSR representative complex, the cardiac complex from the second cardiac signal is morphologically compared to the second NSR  
10 representative complex. In the present embodiment, this comparison is then used to classify the cardiac complex as either a complex representative of an arrhythmic episode or of a non-arrhythmic episode.

Through the process of first aligning the cardiac complex sensed in the first cardiac signal with the first NSR representative complex, the  
15 comparison of the cardiac complex as sensed in the second cardiac signal to the second NSR representative complex not only uses the relative morphologies of the cardiac complexes in classifying the cardiac complex, but also takes into consideration the relative time the cardiac complex detected in the first cardiac signal occurred with respect to the cardiac complex detected in the second  
20 cardiac signal. The relative time between the sensed cardiac complex in the first cardiac signal and the second cardiac signal helps to further accentuates morphological differences in the cardiac complex and template cardiac complex.

Referring now to Figure 5 of the drawings, there is shown one embodiment of a medical device system suitable for implementing the present  
25 subject matter. By way of example only, and not by limitation, the medical device system includes an implantable cardiac defibrillator 500 electrically and physically coupled to at least one catheter 502. In one embodiment, the catheter 502 is an intracardiac catheter which includes at least a first cardiac electrode and a second cardiac electrode.

30 The catheter 502 is implanted in a human body 504 with portions of the catheter 502 inserted into a heart 506 to detect and analyze electric cardiac signals produced by the heart 506 and to provide electrical energy to the heart

506 under certain predetermined conditions to treat cardiac arrhythmias, including ventricular fibrillation, of the heart 506.

In one embodiment, the catheter 502 is an endocardial lead adapted to be releasably attached to the cardiac defibrillator 500. The catheter 502 has an elongate body with a proximal end 508 and a distal end 510, and includes at least a first cardiac electrode and a second cardiac electrode. In one embodiment, the catheter 502 has a pacing electrode 512 located at, or adjacent, the distal end 510 of the catheter 502. Additional pacing electrodes can also be included on the catheter 502 to allow for bipolar sensing and pacing with the pacing electrode 512. In addition, other pacing and sensing electrode configurations are also possible. The catheter 502 also includes one or more defibrillation electrodes. In one embodiment, the catheter 502 has a first defibrillation electrode 514 and a second defibrillation electrode 516, where the defibrillation electrodes have a coil construction as is known.

In addition to the catheter configuration shown in Figure 5, it is considered within the scope of the present subject matter that additional catheters positioned in or around the ventricular and/or the atrial chambers can be added to the cardiac defibrillator 500 to allow for additional cardiac signals to be sensed (e.g., two or more cardiac signals). Thus, it would be possible to sense cardiac signals from any combination or subcombination of ventricular, right ventricular, left ventricular, atrial, right atria and/or left atria locations. These signals can include, but are not limited to, far-field and/or near-field cardiac signals.

Referring now to Figure 6, there is shown an embodiment of a block diagram of a cardiac defibrillator 500. The cardiac defibrillator 500 includes control system circuitry 600 for receiving cardiac signals from a heart 506 and delivering electrical energy to the heart 506. The control system circuitry 600 includes a sensing system 602 attached to at least one catheter. The sensing system 602 includes terminals labeled with reference numbers 604, 608, and 612 for connection to electrodes attached to the surface of the catheter 502. In one embodiment, the pacing electrode 512 is electrically connected to terminal 604 and to the control system circuitry 600 through an electrically insulated conductor provided within the elongate body of the catheter 502. The first defibrillation electrode 514 and the second defibrillation electrode 516 are

connected to terminals 608 and 612, respectively, and to the control system circuitry 600 through electrically insulated conductors provided within the elongate body of the catheter 502.

In one embodiment, the control system circuitry 600 of the cardiac  
5 defibrillator 500 is encased and hermetically sealed in a housing 530 suitable for implanting in a human body as are known in the art. A connector block 532 (Figure 5) is additionally attached to the housing 530 of the cardiac defibrillator 500 to allow for the physical and the electrical attachment of the catheter 502 and the electrodes to the cardiac defibrillator 500 and the encased control system  
10 circuitry 600.

In one embodiment, the control system circuitry 600 of the cardiac defibrillator 500 is a programmable microprocessor-based system, with a microprocessor 616 and a memory circuit 620 which contains parameters for various pacing, defibrillation, and sensing modes and stores data indicative of  
15 cardiac signals received by the control system circuitry 600. A transmitter circuit 624 is additionally coupled to the control system circuitry 600 and the memory circuit 620 to allow the cardiac defibrillator 500 to communicate with and receive programming instructions and transmit data to and from a programmer unit 228 as is known in the art. In one embodiment, the transmitter  
20 circuit 624 and the programmer unit 628 use a wire loop antenna 632 and a radio frequency telemetric link, as is known in the art, to receive and transmit signals and data to and from the programmer unit 628 and the control system circuitry 600. In this manner, programming commands or instructions are transferred to the microprocessor 616 of the cardiac defibrillator 500 after implant, and stored  
25 cardiac data pertaining to sensed arrhythmic episodes within the heart 506 and subsequent therapy, or therapies, applied to correct the sensed arrhythmic event are transferred to the programmer unit 628 from the cardiac defibrillator 500.

In the present embodiment, the medical device system senses at least a first signal and a second signal, both of which are representative of  
30 electrical cardiac activity. The first signal and the second signal each contain cardiac complexes which represent at least a portion of the cardiac cycle. Based on the embodiment shown in Figure 5, the first signal is a rate signal sensed within the right ventricle chamber of the heart and the second signal is a

morphology signal sensed across at least a portion of the ventricular region of the heart. In an alternative embodiment, the first and second signals can be rate and morphology signals sensed in a supraventricular region of the heart.

Alternatively, cardiac electrodes and/or catheters can be provided to allow for the  
5 first signal to be a morphology signal and the second signal to be a rate signal.

In the embodiment shown in Figure 5, the pacing electrode 512 is included in a near-field channel which senses near-field signals or rate-signals of the heart 506. The near-field sensing channel includes the pacing electrode 512 which is coupled to a sense amplifier 630 within the sensing system 602. In one  
10 embodiment, the housing 530 of the cardiac defibrillator 500 is coupled to the sense amplifier 630 at 634 to allow for unipolar cardiac rate sensing between the pacing electrode 512 and the housing 530 of the cardiac defibrillator 500. In an alternative embodiment, the cardiac rate signal is sensed using pacing electrode 512 and the first defibrillation electrode 514.

15 The output of the sense amplifier 630 is shown connected to an R-wave detector 636. The R-wave detector 636 serves to sense and amplify cardiac signals, including cardiac complexes, sensed from the heart, and apply signals indicative thereof to a signal feature comparison circuit 638. The signal feature comparison circuit 638 is coupled to the microprocessor 616. Among other  
20 things, microprocessor 616 responds to signals from the R-wave detector 636 by providing pacing signals to a pace output circuit 640, as needed according to the programmed pacing mode. In one embodiment, the pace output circuit 640 provides output pacing signals to terminals 604 and 634, which connect to the pacing electrode 512 and the housing 530 of the cardiac defibrillator 500, for  
25 cardiac pacing.

Referring again to the embodiment in Figure 5, far-field or morphology signals are sensed through the first defibrillation electrode 514 and the second defibrillation electrode 516. The first defibrillation electrode 514 and the second defibrillation electrode 516 are used in a far-field sensing channel,  
30 where the first defibrillation electrode 514 and the second defibrillation electrode 516 are coupled to a sense amplifier 644 to sense far-field signals, which include cardiac complexes, from the heart. In an alternative embodiment, far-field signals are sensed between the first defibrillation electrode 514, the second

defibrillation electrode 516 and the housing 530. The output of the sense amplifier 644 is coupled to a morphology analyzer circuit 648.

The morphology analyzer circuit 648 receives and processes the cardiac complexes detected within the cardiac signals. In one embodiment, the morphology analyzer circuit 648 receives cardiac signals, including cardiac complexes representative of the cardiac cycle from the sensing system. Cardiac complexes analyzed by the morphology analyzer circuit 648 can include detected P-waves, QRS-complexes, and R-waves. In one embodiment, the morphology analyzer circuit 648 includes an analog filter for filtering cardiac signal noise sensed by the electrodes. The cardiac signals are then bandlimited before arriving at an analog-to-digital filter which converts the analog signals into digital signals suitable for processing. In an alternative embodiment, the cardiac signals are filtered through an analog peak detector to extract the maximum and minimum cardiac signal values for each sensed cardiac complex.

In processing sensed cardiac complexes, the morphology analyzer circuit 648 windows a cardiac complex sensed in two or more cardiac signals. In one embodiment, the morphology analyzer circuit 648 locates and extracts information from one or more predetermined features of sensed cardiac complexes. As previously discussed, the type of information extracted by the morphology analyzer circuit 648 can include the time of occurrence of a predetermined feature and the amplitude value of a predetermined feature. In one embodiment, the predetermined features include repeatably identifiable portions of cardiac complexes which are repeatably identifiable in subsequent cardiac complexes. For example, features include a maximum deflection of the cardiac complex, a beginning of a cardiac complex as indicated by a predetermined deviation of the cardiac signal from a baseline signal, and an ending of a cardiac complex as indicated by a return of the first cardiac signal to a baseline signal. In one embodiment, the features are selectively programmed into the medical device system.

A template generator circuit 650 is coupled to the sensing system 602. The template generator circuit 650 receives information from the morphology analyzer 648. In one embodiment, the information received from the morphology analyzer 648 includes the information extracted from the two or

more cardiac signals by the morphology analyzer circuit 648. In one embodiment, the template generator circuit 650 creates the numerical representation of sensed cardiac complexes. The template generator circuit 650 then creates the "N" dimensional cardiac complex vector from these values as previously described. In addition, the template generator circuit 650 is also used to create the one or more classification vectors from a patient's own cardiac complexes as previously described.

In an alternative embodiment, the template generator circuit 650 receives at least the first signal and the second signal sensed from the heart 506. In one embodiment, the template generator circuit 650 determines a first normal sinus rhythm (NSR) representative complex and a second NSR representative complex from a plurality cardiac complexes sensed during normal sinus rhythm. In one embodiment, the first NSR representative complex and the second NSR representative complex are averages of cardiac complexes sensed in the first signal and the second signal during a patient's normal sinus rhythm. In an alternative embodiment, the first NSR representative complex and the second NSR representative complex are median values of the cardiac complexes sensed in the first signal and the second signal during a patient's normal sinus rhythm.

After the cardiac signals and information relating to the cardiac complexes in the cardiac signals have been processed by the morphology analyzer circuit 648 and the template generator circuit 650, the signals are received by a signal feature comparison circuit 638. The signal feature comparison circuit 638 uses information contained in the cardiac signals to analyze and classify sensed cardiac complexes.

In one embodiment, the signal feature comparison circuit 638 uses the one or more classification vectors which are stored in memory 620. The signal feature comparison circuit 638 compares the cardiac complex vector to the one or more classification vectors, as previously described, to classify the cardiac complex represented by the cardiac complex vector. In an additional embodiment, the signal feature comparison circuit 638 can also align the cardiac vectors with classification vectors prior to comparing the vectors when programmed to perform this function.

In an alternative embodiment, as cardiac complexes are sensed using the first cardiac signal and the second cardiac signal, the signal feature comparison circuit 638 aligns the predetermined feature in the cardiac complex monitored in the first signal with the predetermined feature on the first NSR representative complex. Once the predetermined features in the cardiac complex from the first signal is aligned with the corresponding predetermined feature in the first NSR representative complex, the morphology analyzer circuit 648 compares the cardiac complex monitored in the second signal to the second NSR representative complex to determine whether the cardiac complex is an arrhythmic complex. In one embodiment, the morphology analyzer circuit 648 compares the morphology of the cardiac complex monitored in the second signal to the second NSR representative complex to determine whether the cardiac complex is an arrhythmic complex.

In an alternative embodiment, the morphology analyzer 648 can also compare the morphology of a cardiac complex sensed in two or more cardiac channels to one or more template cardiac complexes to classify the cardiac complex. In one embodiment, the template cardiac complexes are determined from cardiac complexes sensed in the two or more cardiac channels which are subsequently used to sense cardiac complexes to be classified. Alternatively, the template cardiac complexes are determined from cardiac complexes sensed from a patient population experiencing the cardiac state for which template cardiac complexes are developed. In one embodiment, the cardiac states for which template cardiac complexes can be developed include cardiac rhythms where the left chamber and the right chamber of the ventricles or atria differ by about 20 milliseconds or more, premature ventricular contractions, ischemia, predetermined or custom patterns or classes of complexes predetermined by a physician, arrhythmia, non-arrhythmia, ventricular or supraventricular tachycardia.

In one embodiment, as sensed cardiac complexes are sensed and classified, the microprocessor 616 determines the percentage of classified cardiac complexes for a plurality of sensed cardiac complexes. In one embodiment, the microprocessor 616 determines the percentage of cardiac complexes classified as arrhythmic complexes for a plurality of cardiac complexes sensed during an

arrhythmic episode. In one embodiment, once the percentage of classified cardiac complexes reaches a predetermined threshold for any one of the cardiac conditions or states programmed into the medical device system, the microprocessor 616 responds by providing signals to cardioversion/defibrillation output circuitry 652 to deliver either cardioversion or defibrillation therapy to the heart 506. Power to the cardiac defibrillator 500 is supplied by an electrochemical battery 656 that is housed within the cardiac defibrillator 500.

In addition to the catheter 502, it is possible to add additional electrodes, catheters and the accompanying required circuitry to the medical device system. For example, the cardiac defibrillator 500 can be equipped with electrodes on the surface of the housing 530 to sense surface like cardiac signals. In addition, the medical device system can further include an additional intracardiac catheter implanted in the supraventricular region of the heart. The additional intracardiac catheter includes at least one pacing electrode from which rate signals, or near field signals, from the atria are sensed and pacing pulses are delivered to pace the atrial chamber of the patient's heart. In an additional embodiment, the additional intracardiac catheter is implanted through the coronary sinus vein and down the great cardiac vein to position an electrode, such as a pacing electrode, adjacent to the left ventricular chamber of the heart.

In an alternative embodiment, the catheter 502 is implanted the supraventricular region of the heart for sensing or monitoring cardiac signals from the patient's atrial regions. In one embodiment, a pacing electrode at or adjacent the distal end of the intracardiac catheter is implanted in the coronary sinus vein to allow for rate signals to be sensed from the left atrium. In addition, far-field signals, or morphology signals, are sensed from the supraventricular region of the heart through the first defibrillation electrode and the second defibrillation electrode. In addition to implanting the catheter 502 in the supraventricular region of the heart, an additional atrial catheter can be implanted into the supraventricular region of the heart to allow for additional rate signals, or near-field signals, to be sensed along with the rate signals and morphology signals sensed with the catheter 502. Other intracardiac catheter arrangements and configurations known in the art are also possible and considered to be within the scope of the present system.



Referring now to Figure 7, there is shown an additional embodiment of the present subject matter. At step 700, a cardiac complex is detected during a tachycardia episode in the first signal and the second signal. In one embodiment, tachycardia episodes include, but are not limited to, ventricular  
5 tachycardias and supraventricular tachycardias. In one embodiment, the medical device system analyzes at least the cardiac complexes detected in the first signal to determine the occurrence of a tachycardia episode which will be classified by the present subject matter.

In one embodiment, the first signal and the second signal detect the  
10 occurrence of cardiac cycles through either a near-field sensing channel or a far-field sensing channel as previously discussed. Cardiac complexes sensed in the first signal and the second signals can include the QRS-wave, the R-wave and/or the P-wave of the cardiac complex. This list, however, is not to be taken in a limiting sense as it is recognized that other portions of the cardiac complex can  
15 also be sensed and used with the present subject matter.

As the cardiac complex is detected in the first signal and the second signal during the tachycardia episode, the first and second signal of the cardiac complex are windowed together so the cardiac complex in the first signal is positioned relative to the cardiac complex in the second signal. In other words, the  
20 first signal and the second signal for each sensed tachycardiac cardiac complex are positioned relative to each other according to their occurrence in time.

Figure 8 shows an example of a cardiac complex having been windowed at 800. In the example, 804 shows a tachycardiac cardiac complex monitored on a near-field sensing channel, while 808 shows the cardiac complex  
25 monitored on a far-field sensing channel.

After the cardiac complex has been windowed, the first and second signals of the cardiac complex are positioned or aligned relative to the first NSR representative complex and the second NSR representative complex. In one embodiment, the first and second NSR representative complexes are determined  
30 from a plurality of NSR cardiac complexes detected in the first signal and the second signal, respectively, using the same medical device system that is subsequently used to sense the cardiac complexes. In one embodiment, the first NSR representative complex and the second NSR representative complex are

derived by averaging cardiac complexes detected in the first and second signals for the plurality of NSR cardiac complexes sensed from the patient. In an alternative embodiment, the first NSR representative complex and the second NSR representative complex are derived by taking a median of cardiac  
5 complexes detected in the first and second signals for the plurality of NSR cardiac complexes sensed from the patient.

In addition, the first NSR representative complex and the second NSR representative complex can be updated, either manually or automatically, to reflect changes in a patient's cardiac condition or in the medical device system.  
10 For example, the first NSR representative complex and the second NSR representative complex could change due to the type of drug or dosage of drugs being delivered to the patient and the cardiac disease state of the patient. Therefore, the system can recompute the first NSR representative complex and the second NSR representative complex at regular intervals based either on the  
15 physician's judgement or on the implantable medical devices assessment of the template. Additionally, a safe-check algorithm can be used in conjunction with any automatic updating procedure to ensure that only normal sinus rhythm complexes are used in updating the template.

At 720, the cardiac complex detected in the first signal is aligned  
20 with the first NSR representative complex. In one embodiment, the cardiac complex in the first signal and the first NSR representative complex are aligned around a predetermined feature located in the cardiac complexes. In one embodiment, the predetermined feature includes a repeatably identifiable section, or portion, of the detected cardiac complex that is common to the cardiac  
25 complex detected in the first signal and the first NSR representative complex. In one embodiment, the repeatably identifiable complex section common to the cardiac complex detected in the first signal and the first NSR representative complex is a maximum deflection of the first signal. In one embodiment, the maximum deflection is along an R-wave sensed in the cardiac complex detected  
30 in the first signal and in the first NSR representative complex.

In an alternative embodiment, the repeatably identifiable complex section common to the cardiac complex detected in the first signal and the first NSR representative complex is a predetermined deviation of the first signal from

a baseline signal indicating a beginning of the cardiac complex and the first NSR representative complex. In an additional embodiment, the repeatably identifiable complex section common to the cardiac complex detected in the first signal and the first NSR representative complex is a return of the first signal to a baseline  
5 signal for each of the cardiac complex and the first NSR representative complex for a predetermined time period indicating an ending of the cardiac complex and the first NSR representative complex.

After the cardiac complex detected in the first signal has been aligned with the first NSR representative complex, the cardiac complex detected  
10 in the second signal is compared to the second NSR representative complex to determine whether the cardiac complex is an arrhythmic complex. One way of determining whether the cardiac complex is an arrhythmic complex is to compare the morphology of the second signal to the second NSR representative complex. In one embodiment, the second NSR representative complex has a second NSR  
15 morphology and the cardiac complex detected in the second signal has a second signal morphology. The second NSR morphology of the second NSR representative complex is then compared to the second signal morphology of the second signal to determine whether the cardiac complex is an arrhythmic complex. A variety of techniques exist for morphologic analysis of sensed  
20 cardiac complexes. In one embodiment, the morphology of the cardiac complex sensed in second signal and the morphology of the second NSR representative complex are compared using a correlation waveform analysis, as is known in the art. In addition to correlation waveform analysis, other morphology comparison methods or methods of classifying cardiac complexes sensed during an  
25 arrhythmic episode. Additional morphology analysis techniques include amplitude distribution analysis and spectral analysis. Other morphology analysis techniques are known and are considered to be within the scope of the present subject matter.

By initially aligning the cardiac complex detected in the first signal  
30 with the first NSR representative complex, the time the cardiac complex detected in the second signal and the second NSR representative complex occurred relative to the first signal with the first NSR representative complex become a

factor in determining what portion of the second NSR representative complex is compared to the cardiac complex in the second signal.

Figure 8 shows one embodiment of aligning the cardiac complex detected in the first signal with the first NSR representative complex. In 800  
5 there is shown a window containing a cardiac complex detected in a first signal 804 and a second signal 808. In one embodiment, the first signal 804 is a near-field signal of an R-wave, and the second signal 808 is a far-field signal of a QRS-cardiac complex. In 812 there is shown a window containing a first NSR representative complex 816 and a second NSR representative complex 820. In  
10 the present example, the first NSR representative complex 816 is a near-field signal of an R-wave, and the second NSR representative complex 820 is a far-field signal of a QRS-cardiac complex.

As previously discussed, the morphology analyzer circuit 648 locates the predetermined feature in the cardiac complex detected in the first  
15 signal 804 and in the first NSR representative complex 816. The signal feature comparison circuit 638 then aligns the predetermined feature in the cardiac complex monitored in the first signal 804 with the predetermined feature on the first NSR representative complex 816. In figure 8, the cardiac complex 800 and the first NSR representative complex 812 are aligned around a maximum  
20 deflection 824 of the cardiac complexes 804 and 816. The signal feature comparison circuit 638 then compares the cardiac complex monitored in the second signal 808 to the second NSR representative complex 820 to determine whether the cardiac complex is an arrhythmic complex. As previously discussed, because the predetermined feature in the cardiac complex monitored  
25 in the first signal 804 has been aligned with the predetermined feature on the first NSR representative complex 816, the time the second signal 808 occurs relative the first signal 804 and the time the second NSR representative complex 820 occurs relative the first NSR representative complex 816 can be used to accentuate morphological differences between the complexes. So in one  
30 embodiment, the QRS-cardiac complex 828 in the second signal 808 is morphologically compared to a region 832 along the second NSR representative complex 820. Alternatively, the QRS-cardiac complex 834 in the second NSR

representative complex 820 is morphologically compared to a region 836 along the second signal 808.

Figure 9 shows an alternative embodiment of aligning a cardiac complex sensed during a tachycardia episode with a normal sinus rhythm template cardiac complex. In 900 there is shown a window of a first NSR representative complex 904 and a second NSR representative complex 908. In the present example, the first NSR representative complex 904 is a far-field signal of a QRS-cardiac complex, and the second NSR representative complex 908 is a near-field signal of an R-wave cardiac complex. In 912 there is shown a window of a cardiac complex sensed during a tachycardia episode, where the first signal 916 is a far-field signal of a QRS-cardiac complex and the second signal 920 is a near-field signal of an R-wave cardiac complex.

In the present embodiment, the cardiac complex 912 and the representative NSR complex 900 are aligned around the beginning, or the start, of the cardiac complexes 904 and 916. After the representative NSR complex and the tachycardiac cardiac complex have been aligned, the morphology of the second signal 920 is compared to the morphology of the second NSR representative complex 908 to determine whether the cardiac complex is an arrhythmic complex. In one embodiment, the R-wave cardiac complex 924 in the second signal 920 is morphologically compared to a region 928 along the second NSR representative complex 908. In an alternative embodiment, the R-wave cardiac complex 930 in the second NSR representative complex 908 is morphologically compared to a region 932 along the second signal 920.

In one embodiment, the present subject matter can classify a variety of cardiac complexes, including VT-complexes, SVT-complexes and NSR-complexes. Other classifications for the tachycardiac cardiac complex are known and are considered within the scope of the present invention.

Figure 10 shows an additional embodiment of the present subject matter. At 1000, a first signal and a second signal representative of electrical cardiac activity are sensed from a patient. In one embodiment, each of the signals include cardiac complexes representative of cardiac cycles. At 1010, a plurality normal sinus rhythm (NSR) cardiac complexes are detected in the first signal and the second signal. In one embodiment, the medical device system

determines the first NSR representative complex from the plurality of NSR cardiac complexes detected in the first signal and determines the second NSR representative complex from the plurality of NSR cardiac complexes detected in the second signal. The first and second NSR representative complexes are then  
5 stored in the memory of the medical device system.

At 1020, cardiac complexes monitored in at least the first signal are analyzed by the medical device system to detect the onset of a tachycardia episode. If no tachycardia episode is detected, the system continues to sense cardiac signals and analyzes them for the occurrence of a tachycardia episode. In  
10 one embodiment, the occurrence of a tachycardia episode is based on the cardiac rate, where a tachycardia episode is declared when the cardiac rate exceeds a predetermined threshold. In one embodiment, the predetermined threshold is a cardiac rate of between 150 and 180 beats per minute. Other systems of determining the occurrence of a tachycardia episode are known and are  
15 considered to be within the scope of the present system.

When a tachycardia episode is detected the system then proceeds to 1030. At 1030, the first signal and the second signal are monitored for the occurrence of cardiac complexes. The detected cardiac complexes are analyzed, or processed, so that each cardiac complex is classified as either an arrhythmic  
20 complex or a non-arrhythmic complex. In processing each cardiac complex at 1030, the predetermined feature is located in the cardiac complex detected in the first signal and the first NSR representative complex. As previously discussed, the predetermined feature includes a repeatably identifiable portion of cardiac complexes.

25 At 1040, the predetermined feature on the cardiac complex sensed in the first signal is then aligned with the corresponding first feature found on the first NSR representative complex. In one embodiment, the predetermined feature on the first NSR representative complex has been previously located and stored in the memory of the medical device system. After the predetermined  
30 feature on both the cardiac complex sensed in the first signal and the first NSR representative complex have been aligned, the cardiac complex sensed in the second signal is compared to the second NSR representative complex at 1050. In one embodiment, the second NSR representative complex has a second NSR

morphology and the cardiac complex detected in the second signal has a second signal morphology, where the second NSR morphology is compared to the second signal morphology to determine whether the cardiac complex is an arrhythmic complex. Based on the comparison, the cardiac complex is classified  
5 as either an arrhythmic complex or as a non-arrhythmic complex at 1060.

After making a determination as to whether a cardiac complex is an arrhythmic complex or a non-arrhythmic complex, a percentage of arrhythmic complexes is determined at 1070. At 1080, the calculated percentage of arrhythmic complexes is compared to a predetermined percentage threshold. In  
10 one embodiment, therapy for treating the condition associated with the arrhythmic complexes being sensed is applied to the patient's heart at 1090 when the percentage of arrhythmic complexes exceeds the predetermined percentage threshold. If the percentage of arrhythmic complexes does not exceed the predetermined percentage threshold, the system returns to 1030. In one  
15 embodiment, the predetermined percentage threshold is a programmable value in the range of 40 to 60 percent, where a value of approximately 50 percent is an acceptable value.

Figure 11 shows an additional embodiment of the present subject matter. At 1100, a first signal and a second signal representative of electrical  
20 cardiac activity are sensed from a patient, where the first signal and the second signal each include at least a portion of a QRS-complex. At 1110, a plurality normal sinus rhythm (NSR) cardiac complexes are detected in the first signal and the second signal. The medical device system determines the first NSR representative complex from the at least a portion of the QRS-complex in each of  
25 the plurality of NSR cardiac complexes detected in the first signal and the second NSR representative complex from the at least a portion of the QRS-complex in each of the plurality of NSR cardiac complexes detected in the second signal. The first and second NSR representative complexes are then stored in the memory of the medical device system.

30 At 1120, cardiac complexes monitored in at least the first signal are analyzed by the medical device system to detect the onset of a tachycardia episode. If no tachycardia episode is detected, the system continues to sense cardiac signals and analyzes them for the occurrence of a tachycardia episode. In

one embodiment, the occurrence of a tachycardia episode is based on the ventricular cardiac rate, where a tachycardia episode is declared when the ventricular cardiac rate exceeds a predetermined threshold. In one embodiment, the predetermined threshold is a ventricular cardiac rate of between 150 and 180  
5 beats per minute. Other systems of determining the occurrence of a tachycardia episode are known and are considered to be within the scope of the present system.

When a tachycardia episode is detected the system then proceeds to 1130. At 1130, the first signal and the second signal are monitored for the  
10 occurrence of cardiac complexes. The detected cardiac complexes are analyzed, or processed, so that each cardiac complex is classified as either a ventricular tachycardia complex or a non-ventricular tachycardia complex. In processing each cardiac complex at 1130, the predetermined feature is located in the cardiac complex detected in the first signal and the first NSR representative complex.  
15 As previously discussed, the predetermined feature includes a repeatably identifiable portion of cardiac complexes.

At 1140, the predetermined feature on the cardiac complex sensed in the first signal is then aligned with the corresponding first feature found on the first NSR representative complex. In one embodiment, the predetermined  
20 feature on the first NSR representative complex has been previously located and stored in the memory of the medical device system. After the predetermined feature on both the cardiac complex sensed in the first signal and the first NSR representative complex have been aligned, the cardiac complex sensed in the second signal is compared to the second NSR representative complex at 1150.  
25 In one embodiment, the second NSR representative complex has a second NSR morphology and the cardiac complex detected in the second signal has a second signal morphology, where the second NSR morphology is compared to the second signal morphology to determine whether the cardiac complex is a ventricular tachycardia complex or a non-ventricular tachycardia complex.  
30 Based on the comparison, the cardiac complex is classified as either a ventricular tachycardia complex or a non-ventricular tachycardia complex at 1160.

After making a determination as to whether a cardiac complex is a ventricular tachycardia complex or a non-ventricular tachycardia complex, a



percentage of ventricular tachycardia complexes is determined at 1170. At 1180, the calculated percentage of ventricular tachycardia complexes is compared to a predetermined percentage threshold. In one embodiment, therapy for treating a ventricular tachycardia is applied to the patient's heart at 1190 when the  
5 percentage of ventricular tachycardia complexes exceeds the predetermined percentage threshold. If the percentage of ventricular tachycardia complexes does not exceed the predetermined percentage threshold, the system returns to 1130. In one embodiment, the predetermined percentage threshold is a programmable value in the range of 40 to 60 percent, where a value of  
10 approximately 50 percent is an acceptable value.

Figure 12 shows an additional embodiment of the present subject matter. At 1200, a first cardiac signal and a second cardiac signal representative of electrical cardiac activity are sensed and monitored from a patient. In one embodiment, the first cardiac signal and the second cardiac signal are monitored  
15 from a first cardiac region and a second cardiac region, respectively. At 1210, cardiac complexes are detected in the first cardiac signal and the second cardiac signal. As the cardiac complexes are sensed, template morphologies are developed for cardiac conditions exhibited by the patient. In one embodiment, as the patient experiences a cardiac condition (such as a ventricular tachycardia or supraventricular tachycardia) the cardiac complexes are recorded. In one  
20 embodiment, the system can then use the recorded cardiac complexes to develop a template morphology for the cardiac condition.

In one embodiment, the template morphology is comprised of a first template morphology and a second template morphology. In one  
25 embodiment, the first template morphology is derived from cardiac complexes monitored in the first cardiac signal sensed from approximately the first cardiac region and the second template morphology is derived from cardiac complexes monitored in the second cardiac signal sensed from approximately the second cardiac region. In an alternative embodiment, the first template morphology and  
30 the second template morphology for each cardiac condition of interest are developed through groups of patient data and programmed into the memory of the medical device system. The template cardiac complexes are then stored in the memory of the medical device system.

In one embodiment, the patient's cardiac complexes are monitored and analyzed by the medical device system. In one embodiment, the cardiac complexes are monitored for the onset of a tachycardia event. In an alternative embodiment, the cardiac complexes are monitored to detect the occurrence of a predetermined class or type of cardiac complex (e.g., PVCs, ischemic complexes). In one embodiment, to determine the occurrence of the predetermined class of cardiac complexes, the cardiac complexes sensed in the cardiac signals are morphologically compared to the template cardiac complexes.

For the present embodiment, the morphology of the cardiac complex in the first cardiac signal is compared to the first template morphology at 1220. At 1230, the morphology of the cardiac complex in the second cardiac signal is compared to the second template morphology of a cardiac condition template morphology. Based on the comparison, the sensed cardiac complexes are then classified as either belonging to or not belonging to one or more of the classes of cardiac complexes represented by the template cardiac complexes at 1240. After classifying each cardiac complex, the medical device system can retain the sensed cardiac complexes in memory. In addition, a percentage of the classified complexes is determined at 1070.

In an additional embodiment, a third cardiac signal containing the cardiac complex can be monitored. A third template morphology can be developed in the same manner as described for the first and second template morphologies. The morphology of the cardiac complex in the third cardiac signal is then compared to a third template morphology. So, the cardiac complex can be classified based on the comparison of the morphology of the cardiac complex in the first cardiac signal, the second cardiac signal and the third cardiac signal to the first template morphology, the second template morphology and the third template morphology.

## WHAT IS CLAIMED IS:

1. A system, comprising:
  - at least one lead adapted to sense signals;
  - a sensing system attached to the at least one lead, where the sensing
  - 5 system senses a first signal and a second signal;
  - a morphology analyzer circuit coupled to the sensing system,
  - wherein the morphology analyzer circuit locates a position of at least one
  - predetermined feature of the complex in the first signal and the second
  - signal and generates two or more scalar values as a function of the position
  - 10 of the at least one predetermined feature for each of the first signal and the
  - second signal; and
  - a template generator coupled to the morphology analyzer, wherein
  - the template generator circuit creates a vector from the two or more scalar
  - values generated by morphology analyzer circuit.
  - 15
2. The system of claim 1, where the template generator circuit determines a
- first representative complex and a second representative complex from a
- plurality complexes sensed during a normal rhythm.
- 20
3. The system of claim 2, where the morphology analyzer circuit locates the
- predetermined feature in the complex detected in the first signal and in the first
- representative complex, where the predetermined feature includes a repeatably
- identifiable complex section common to the complex detected in the first signal
- and the first representative complex.
- 25
4. The system of claim 3, including a signal feature comparison circuit
- coupled to the morphology analyzer circuit and the template generator circuit,
- where the signal feature comparison circuit aligns the predetermined feature in
- the complex monitored in the first signal with the predetermined feature on the
- 30 first representative complex and compares the complex monitored in the second
- signal to the second representative complex to determine whether the complex is
- a rapid complex.

5. The system of claim 4, where the morphology analyzer circuit locates the predetermined feature at a maximum deflection of the complex detected in the first signal and in the first representative complex.
- 5 6. The method of claim 5, where the maximum deflection is along a wave sensed in the complex detected in the first signal and in the first representative complex.
7. The system of claim 4, where the morphology analyzer circuit  
10 locates the predetermined feature at a beginning of the complex detected in the first signal and the first representative complex as indicated by a predetermined deviation of the first signal from a baseline signal.
8. The system of claim 4, where the morphology analyzer circuit  
15 locates the predetermined feature at an ending of the complex detected in the first signal and the first representative complex as indicated by a return of the first signal to a baseline signal for a predetermined time period.
9. The system of claim 4, where the sensing system includes a far-  
20 field sensing channel over which the first signal is monitored and a near-field sensing channel over which the second signal is monitored.
10. The system of claim 4, where the sensing system includes a near-  
field sensing channel over which the first signal is monitored and a far-  
25 field sensing channel over which the second signal is monitored.
11. The system of claim 4, where the second representative complex  
has a second morphology and the complex detected in the second signal  
has a second signal morphology, and the signal feature comparison circuit  
30 compares the second morphology to the second signal morphology to determine whether the complex is a rapid complex.

12. The system of claim 11, where the signal feature comparison circuit uses a correlation waveform analysis algorithm to compare the second morphology to the second signal morphology.
- 5 13. The system of claim 4, where the sensing system senses at least a portion of a complex in the first signal and the second signal, the template generator circuit determines the first representative complex and the second representative complex from the at least a portion of the complexes sensed during normal rhythm, and the signal feature comparison circuit  
10 compares the complex monitored in the second signal to the complex in the second representative complex to determine whether the complex is a rapid complex.
14. The system of claim 13, where the signal feature comparison  
15 circuit determines a percentage of rapid complexes for a plurality of complexes, and the control system determines therapy when the percentage of rapid complexes exceeds a predetermined percentage threshold.
15. The system of claim 14, where the predetermined percentage  
20 threshold is 50 percent.
16. The system of claim 1, including a signal feature comparison circuit coupled to the morphology analyzer circuit and the template generator circuit, wherein the signal feature comparison circuit compares  
25 the vector to one or more classification vectors to classify the complex.
17. The system of claim 16, wherein the at least one predetermined feature is a maximum deflection of the first signal and the second signal.
- 30 18. The system of claim 16, wherein the at least one predetermined feature is a predetermined deviation of the of the first signal and the second signal from a baseline signal indicating a beginning of the complex.

19. The system of claim 16, wherein the at least one predetermined feature is a return of the first signal and the second signal to a baseline signal for a predetermined time period indicating an ending of the complex.
- 5 20. The system of claim 16, wherein the scalar value is a time the at least one predetermined feature in the morphology of the complex occurred.
- 10 21. The system of claim 16, wherein the scalar value is a difference in time between the occurrence of a first predetermined feature and a second predetermined feature.
- 15 22. The system of claim 16, wherein the scalar value is a magnitude of the position of the at least one predetermined feature of the first signal and the second signal.
- 20 23. The system of claim 16, wherein the signal feature comparison circuit determines a similarity coefficient for each comparison of the vector to the one or more classification vectors, and classifies the complex as a predetermined condition when the similarity coefficient exceed a predetermined threshold.
- 25 24. The system of claim 16, wherein the signal feature comparison circuit aligns the vector with each of the one or more classification vectors prior to comparing the vectors, where the vector includes element positions occupied by the scalar values, and each of the one or more classification vectors includes an equal number of element positions as the element positions of the vector, wherein the element positions of the one or more classification vectors are occupied by scalar values representing the predetermined condition, and wherein the vector is aligned with a classification vector of the one or more classification vectors by adjusting each scalar value of the vector so one of the element positions of the vector
- 30

equals a scalar value in a corresponding element position in a classification vector.

25. A method, comprising:
- 5            monitoring two or more signals;  
             detecting a complex in each of the two or more signals;  
             comparing a morphology of the complex in each of the two or more  
signals to the morphology of a template complex; and  
             classifying the complex based on the comparison of the  
10 morphology of the complex in each of the two or more signals to the  
morphology of the template complex.
26.            The method of claim 25, wherein monitoring two or more signals  
includes monitoring a first signal and a second signal;
- 15            analyzing the at least the first signal to detect an episode;  
             when the episode is detected, detecting the complex in the first  
signal and the second signal;
- wherein comparing the morphology includes locating a  
predetermined feature in the complex detected in the first signal and a first  
20 representative complex, wherein the predetermined feature includes a  
repeatably identifiable complex section common to the complex detected  
in the first signal and the first representative complex;
- aligning the predetermined feature in the complex detected in the  
first signal and the first representative complex; and
- 25            wherein classifying the complex based on the comparison includes  
comparing the complex detected in the second signal to a second  
representative complex to determine whether the complex is a rapid  
complex.
- 30 27.            The method of claim 26, including detecting a plurality of normal  
complexes in the first signal and the second signal;
- determining the first representative complex from the plurality of  
normal complexes detected in the first signal; and

determining the second representative complex from the plurality of normal cardiac complexes detected in the second signal.

28. The method of claim 26, where the repeatably identifiable complex  
5 section common to the complex detected in the first signal and the first  
representative complex is a maximum deflection of the first signal.
29. The method of claim 28, where the maximum deflection is along a  
10 wave sensed in the complex detected in the first signal and in the first  
representative complex.
30. The method of claim 26, where the repeatably identifiable complex  
15 section common to the complex detected in the first signal and the first  
representative complex is a predetermined deviation of the first signal from  
a baseline signal indicating a beginning of the complex and the first  
representative complex.
31. The method of claim 26, where the repeatably identifiable complex  
20 section common to the complex detected in the first signal and the first  
representative complex is a return of the first signal to a baseline signal for  
each of the complex and the first representative complex for a  
predetermined time period indicating an ending of the complex and the  
first representative complex.
- 25 32. The method of claim 26, where the second representative complex  
has a second morphology and the complex detected in the second signal  
has a second signal morphology, and comparing the complex detected in  
the second signal to the second representative complex includes comparing  
the second morphology to the second signal morphology to determine  
30 whether the complex is a rapid complex.



33. The method of claim 32, where comparing the second morphology to the second signal morphology includes utilizing a correlation waveform analysis algorithm.
- 5 34. The method of claim 26, where sensing the first signal includes sensing electrical activity through a far-field sensing channel, and sensing the second signal includes sensing electrical activity through a near-field sensing channel.
- 10 35. The method of claim 26, where sensing the first signal includes sensing electrical activity through a near-field sensing channel, and sensing the second signal includes sensing electrical activity through a far-field sensing channel.
- 15 36. The method of claim 26, including detecting at least a portion of a complex in each of the plurality of normal complexes;  
determining the first representative complex from the at least a portion of the complex in each of the plurality of normal complexes detected in the first signal;  
20 determining the second representative complex from the at least a portion of the complex in each of the plurality of normal complexes detected in the second signal;  
comparing a second morphology to the second signal morphology to determine whether the complex is a fast complex;  
25 determining a percentage of the fast complex in a plurality of complexes sensed during the episode; and  
determining therapy when the percentage of the fast complexes exceeds a predetermined percentage threshold.
- 30 37. The method of claim 36, where the predetermined percentage threshold is 50 percent.

38. The method of claim 25, wherein comparing comprises locating at least one predetermined feature in the complex for each of the two or more signals, wherein the at least one predetermined feature includes a repeatably identifiable complex portion;
- 5       generating a scalar value as a function of a position of the at least one predetermined feature for each of the two or more signals;
- using the scalar values to create a vector, where the vector represents the complex; and
- classifying comprises comparing the vector to one or more
- 10       classification vectors, where each of the one or more classification vectors represents a predetermined condition;
- determining a similarity coefficient from each comparison of the vector and the one or more classification vectors; and
- classifying the complex as the predetermined condition when the
- 15       complex similarity coefficient exceed a predetermined threshold.
39. The method of claim 38, where detecting the complex includes isolating the complex in an analysis window.
- 20   40. The method of claim 38, where the at least one predetermined feature in the complex is a maximum deflection of the two or more signals.
41. The method of claim 38, where the at least one predetermined feature in the complex is a predetermined deviation of the two or more
- 25       signals from a baseline signal indicating a beginning of the complex.
42. The method of claim 38, where the at least one predetermined feature in the complex is a return of the two or more signal to a baseline signal for a predetermined time period indicating an ending of the
- 30       complex.
43. The method of claim 38, where the scalar value is a time the at least one predetermined feature of the complex occurred.

44. The method of claim 38, where the scalar value is a difference in time between the occurrence of two of the at least one predetermined feature.
- 5 45. The method of claim 28, where the scalar value is a magnitude of the position of the at least one predetermined feature for each of the two or more signals.
- 10 46. The method of claim 28, where determining a similarity coefficient comprises determining a mean square error value from each comparison of the vector and the one or more classification vectors.
- 15 47. The method of claim 28, including aligning the vector with each of the one or more classification vectors prior to comparing the vector, where the vector includes element positions occupied by the scalar values, and each of the one or more classification vectors includes an equal number of element positions as the element positions of the vector, wherein the element positions of the one or more classification vectors are occupied by scalar values representing the predetermined condition, and wherein the vector is aligned with a classification vector of the one or more classification vectors by adjusting each scalar value of the vector so one of the element positions of the vector equals a scalar value in a corresponding element position in a classification vector.
- 20 48. The method of claim 25, wherein monitoring two or more signals includes monitoring a first signal and a second signal;  
detecting the complex includes detecting the complex in each of the first signal and the second signal;  
comparing the morphology includes comparing the morphology of the complex in the first signal to a first template morphology and  
30 comparing the morphology of the complex in the second signal to a second template morphology; and

classifying the complex includes classifying the complex based on the comparison of the morphology of the complex in the first signal and the second signal to the first template morphology and the second template morphology.

5

49. The method of claim 48, where monitoring the first signal and the second signal comprises monitoring the first signal from a first region and the second signal from a second region.

10 50. The method of claim 48, including deriving the first template morphology from complexes sensed from approximately the first region.

51. The method of claim 48, including deriving the second template morphology from complexes sensed from approximately the second region.

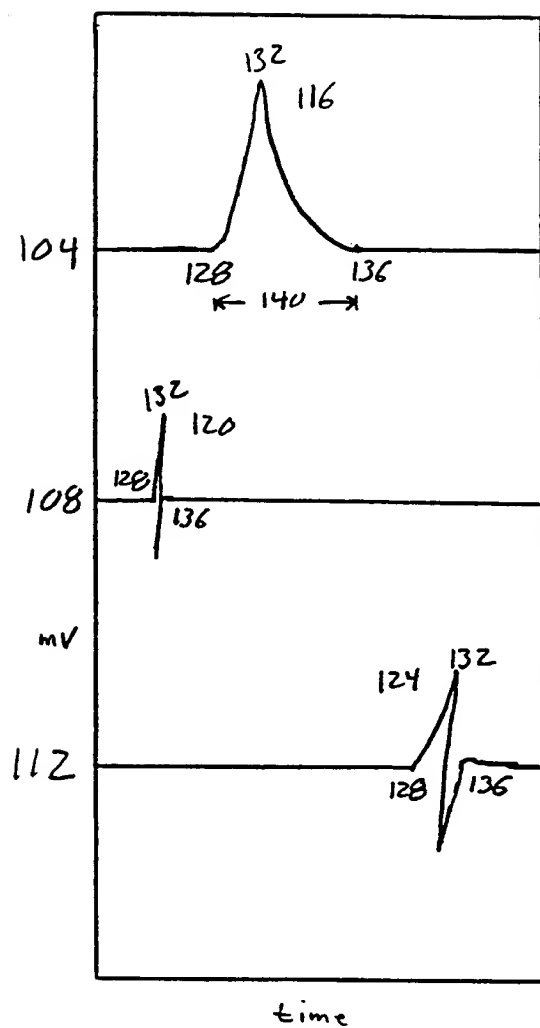
15

52. The method of claim 48, including:  
monitoring a third signal;  
detecting the complex in the third signal;  
20 comparing the morphology of the complex in the third signal to a third template morphology; and  
classifying the complex based on the comparison of the morphology of the complex in the first signal, the second signal and the third signal to the first template morphology, the second template  
25 morphology and the third template morphology.

53. The method of claim 52, where monitoring the third signal comprises monitoring the third signal from a third region.

30 54. The method of claim 53, including deriving the third template morphology from complexes sensed from approximately the third region.

55.           The system or method of any of the forgoing claims, wherein:  
              two or more signals are two or more cardiac signals representative of  
electrical cardiac activity;  
              the complex is a cardiac complex;  
5           the template complex is a template cardiac complex;  
              the episode is a tachycardia episode;  
              the first representative complex is a first normal sinus rhythm  
representative complex;  
              the second representative complex is a second normal sinus rhythm  
10   representative complex;  
              the rapid complex is an arrhythmic cardiac complex;  
              the normal rhythm is a normal sinus rhythm;  
              the normal complexes are normal sinus rhythm complexes;  
              the second morphology is a second normal sinus rhythm morphology;  
15           the portion of the complex is a portion of a QRS-complex;  
              the plurality of complexes is a plurality of normal sinus rhythm cardiac  
complexes;  
              the fast complex is a ventricular tachycardia complex;  
              the first region is a first cardiac region;  
20           the second region is a second cardiac region;  
              the third signal is a third cardiac signal; and  
              the third region is a third cardiac region.



100

Figure 1

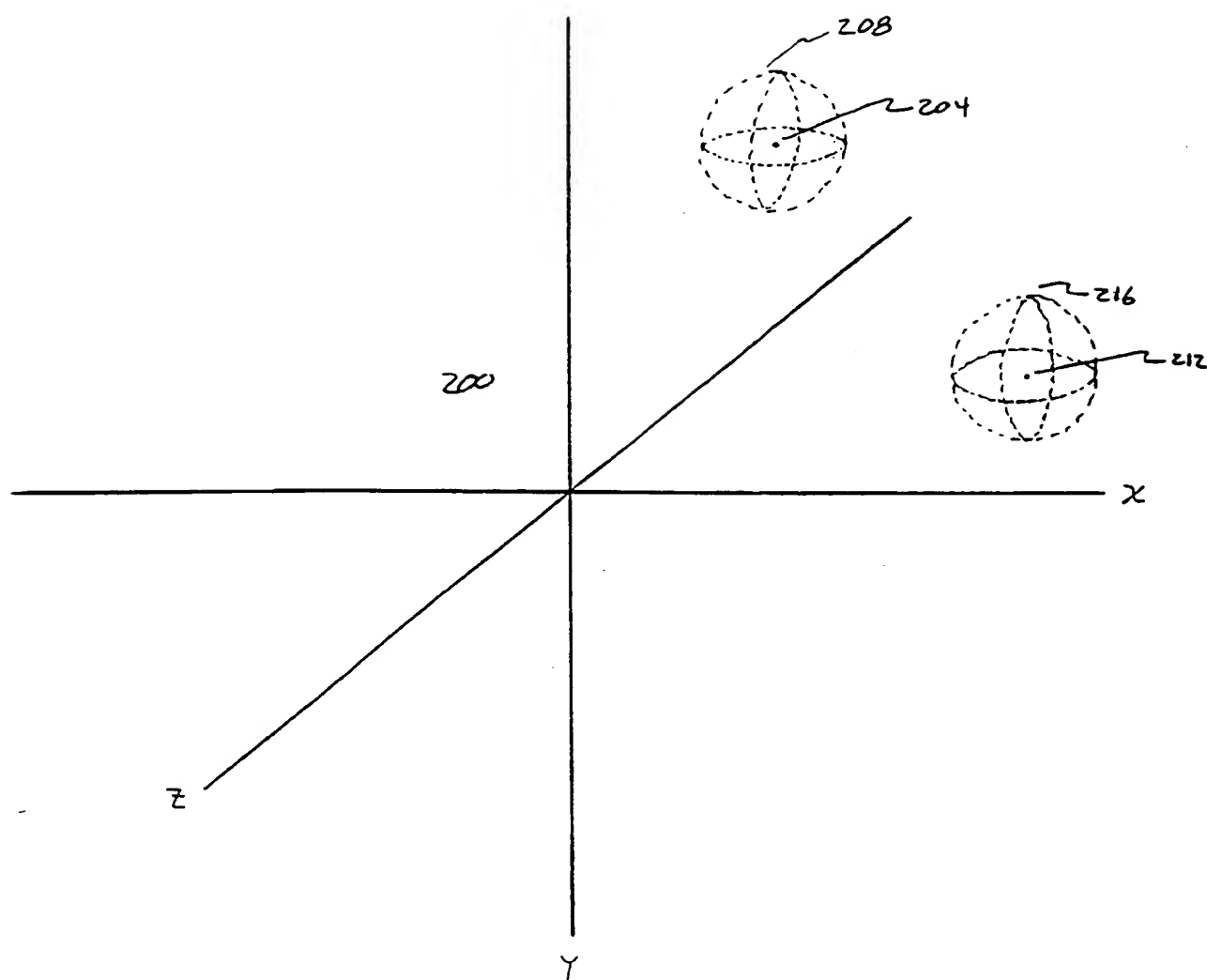


Figure 2

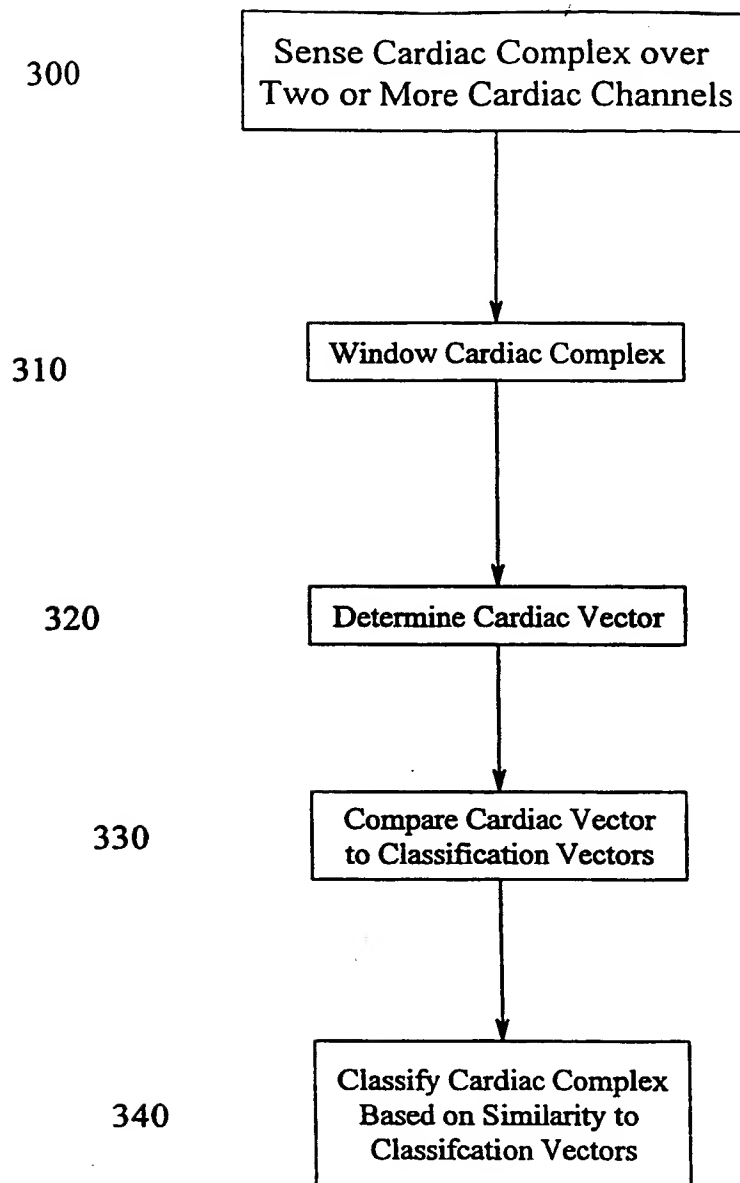


FIGURE 3



4/12

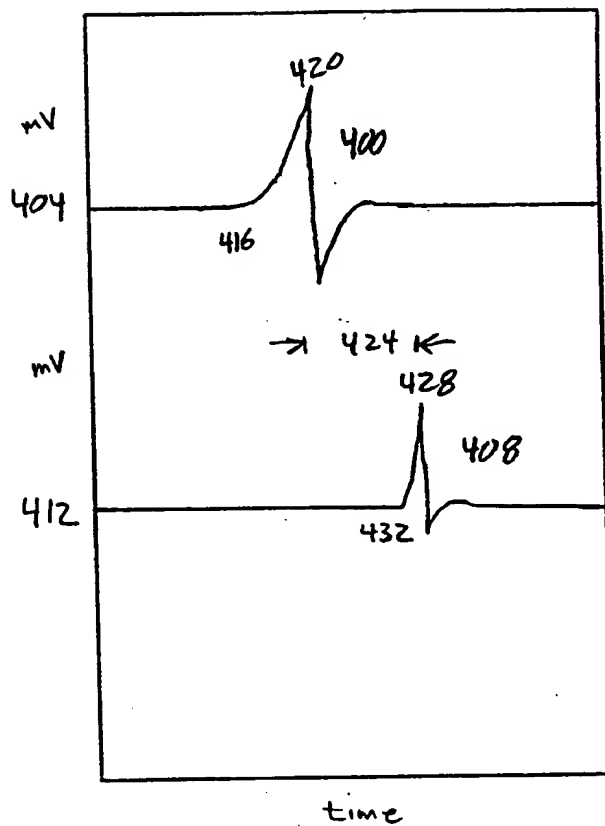


Figure 4

5/12

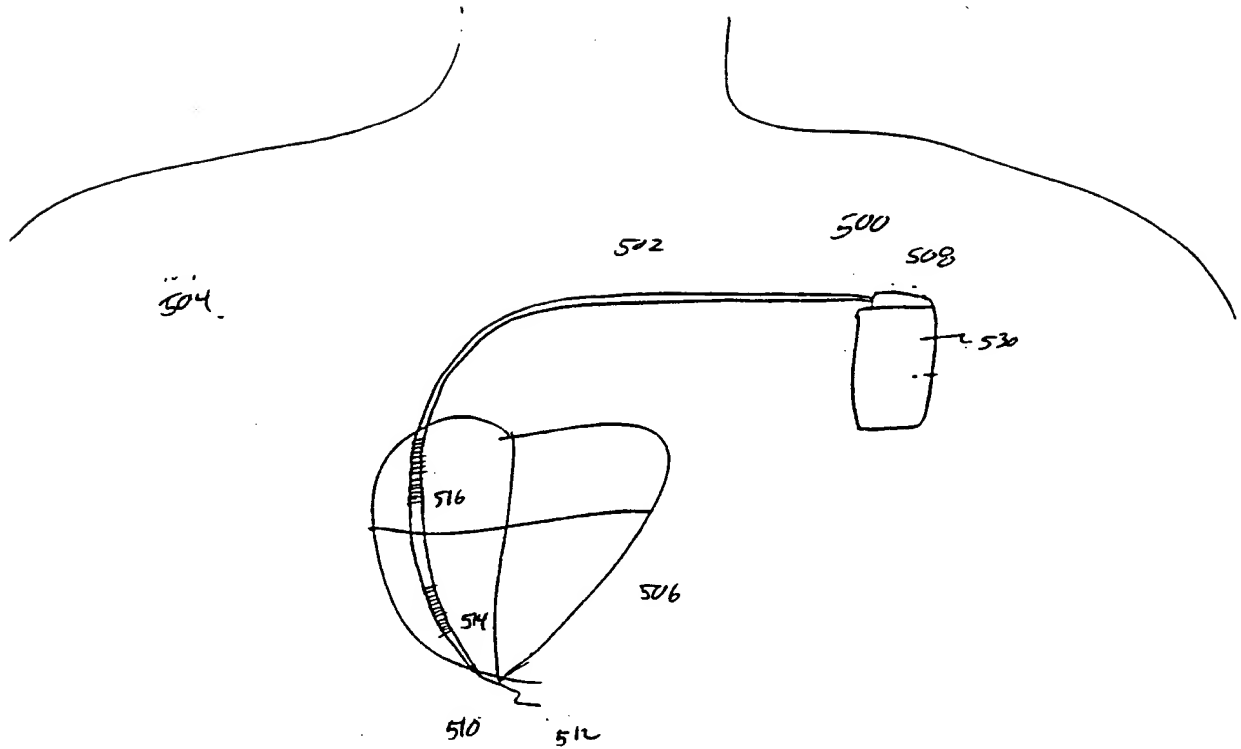


Fig. 5

6/12

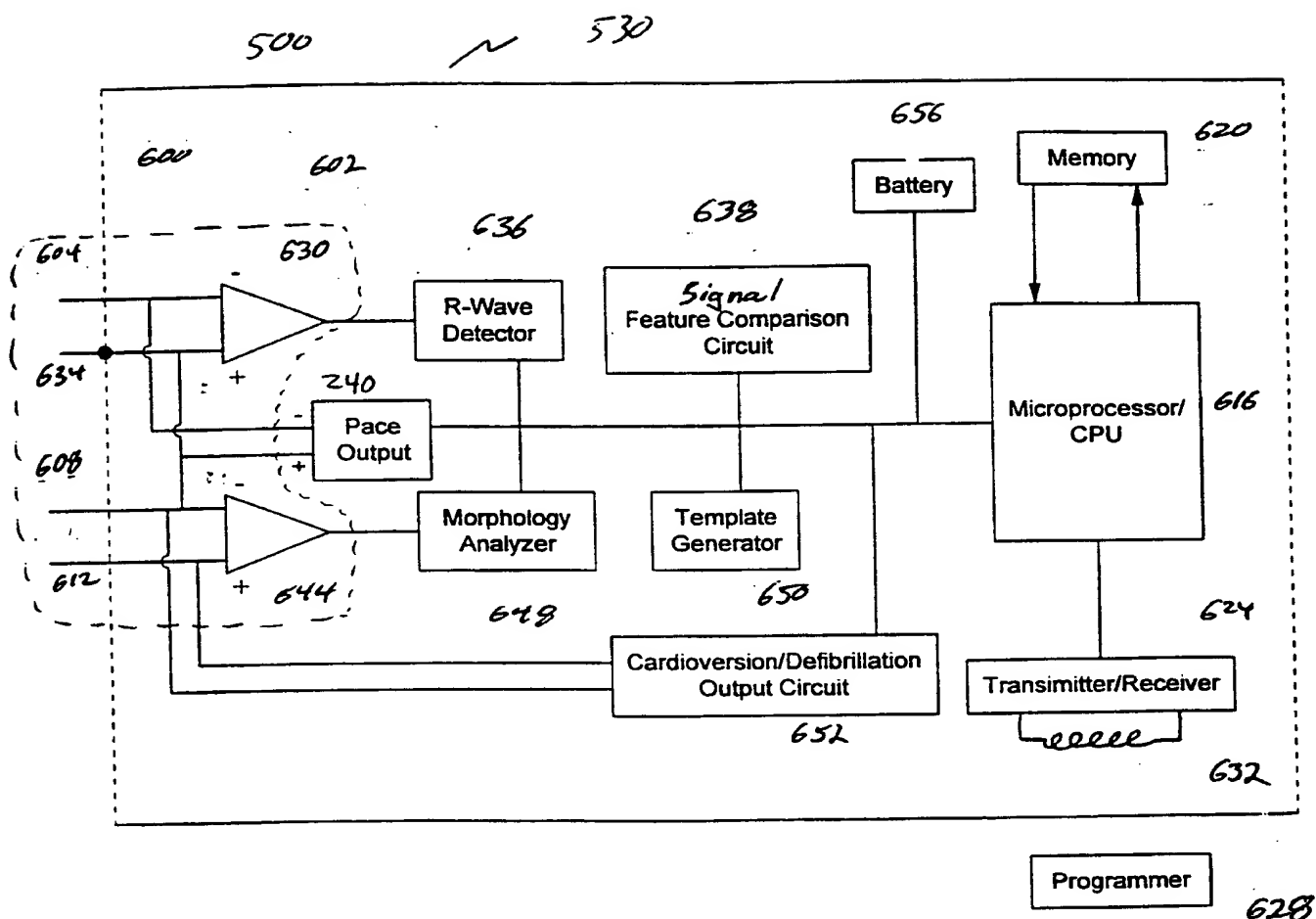


Fig. 6

7/12

700

Sensing a Cardiac Complex From  
a First and a Second Cardiac Signal

720

Aligning the Cardiac Complex From the First Cardiac  
Signal with a First NSR Representative Complex

740

Comparing the Morphology of the Cardiac Complex  
Sensed in the Second Cardiac Signal to the  
Morphology of the Second NSR Representative Complex

FIGURE 7

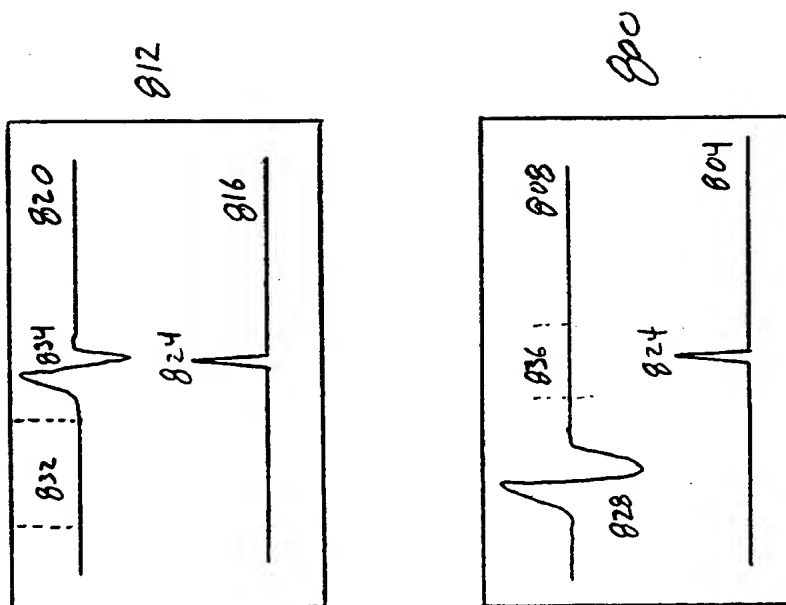


Figure 8

9/12

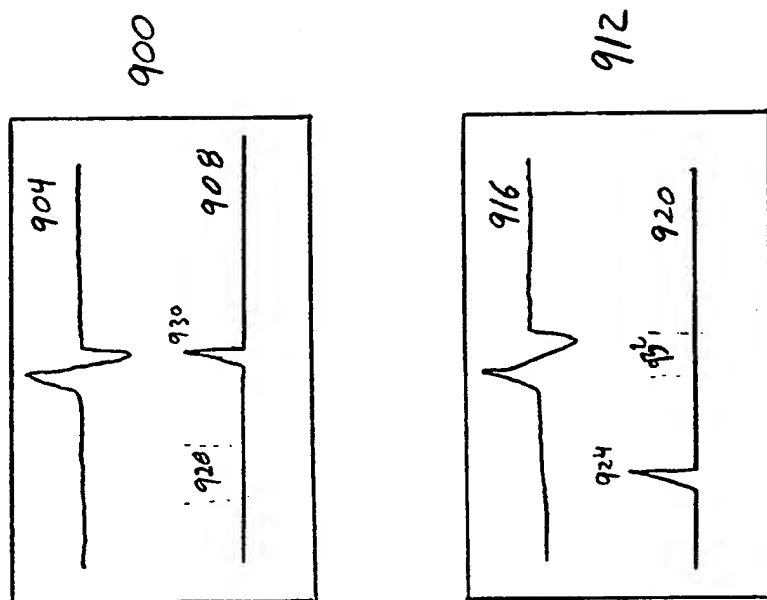


Figure 9

10/12

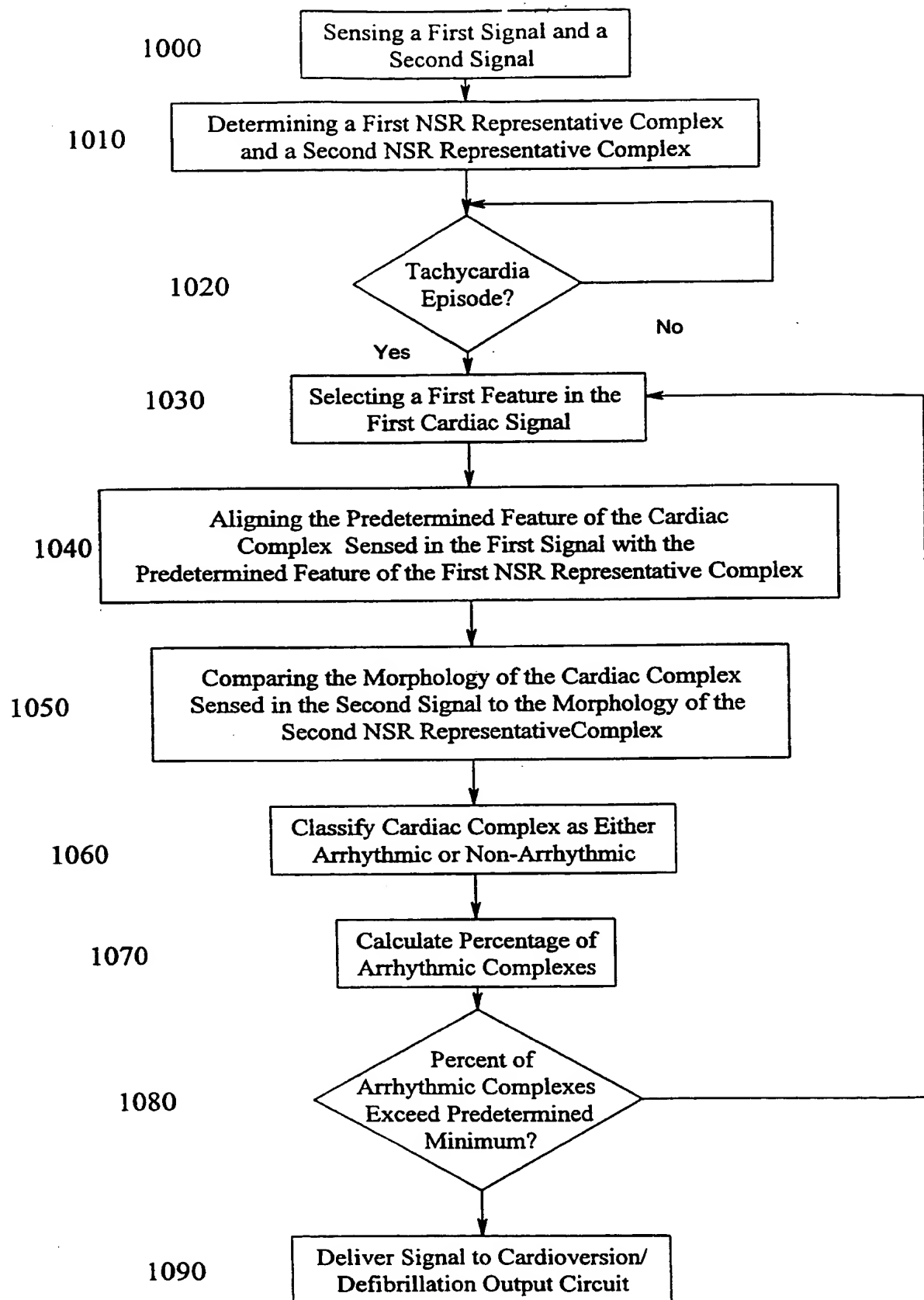


FIGURE 10

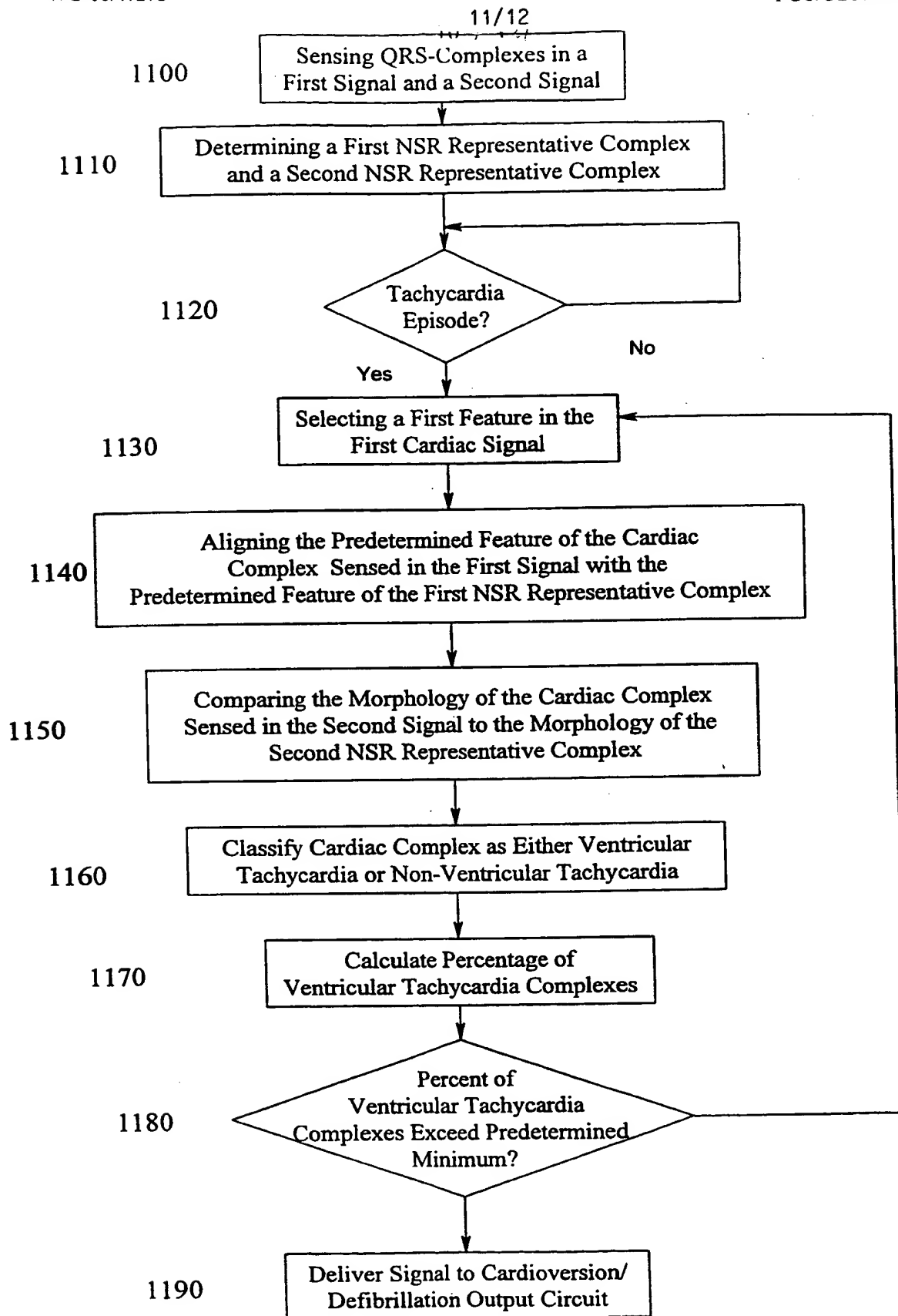


FIGURE 11



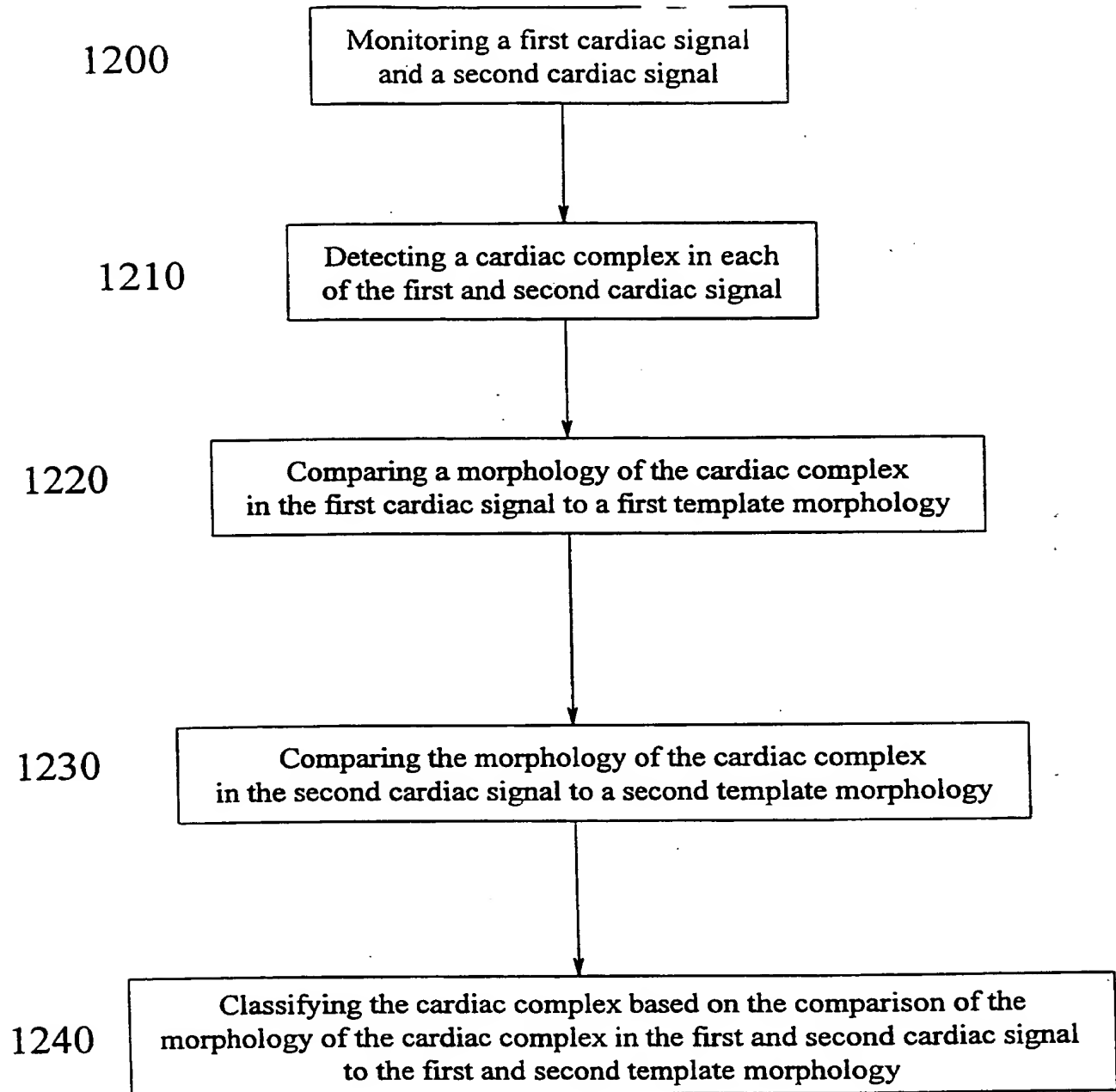


FIGURE 12

# INTERNATIONAL SEARCH REPORT

International Application No  
PCT/US 00/03604

**A. CLASSIFICATION OF SUBJECT MATTER**  
IPC 7 A61N1/37 A61N1/362

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)  
IPC 7 A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	US 5 271 411 A (KAPLAN DANIEL T ET AL) 21 December 1993 (1993-12-21) the whole document	1-4, 16 5-15, 17-24, 55
X A	US 5 193 550 A (DUFFIN EDWIN G) 16 March 1993 (1993-03-16) column 3-15; figures	1-4, 16 5-15, 17-24, 55
X A	US 5 645 070 A (TURCOTT ROBERT) 8 July 1997 (1997-07-08) column 4-6; figures	1-4, 16 5-15, 17-24, 55
X A	US 5 712 801 A (TURCOTT ROBERT) 27 January 1998 (1998-01-27) the whole document	1 2-24, 55
	-/-	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

\* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

Date of the actual completion of the international search

21 July 2000

Date of mailing of the international search report

28/07/2000

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo.nl,  
Fax: (+31-70) 340-3016

Authorized officer

Allen, E

# INTERNATIONAL SEARCH REPORT

national Application No

PCT/US 00/03604

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	US 5 311 874 A (LANG DOUGLAS ET AL) 17 May 1994 (1994-05-17) the whole document	1-4, 16 5-15, 17-24, 55
X A	EP 0 711 531 A (KARLSSON PER ; LUNDAHL GUNILLA (SE); UBBY JOHAN (SE); OLJEMARK MICH) 15 May 1996 (1996-05-15) page 2-7; figures	1-4, 16 5-15, 17-24, 55
X A	US 5 792 065 A (XUE QIUZHEN ET AL) 11 August 1998 (1998-08-11) column 3-7	1-4, 16 5-15, 17-24, 55

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 00/03604

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
US 5271411	A	21-12-1993	JP 6022915	A	01-02-1994
US 5193550	A	16-03-1993	AU 651649	B	28-07-1994
			AU 9112191	A	25-06-1992
			CA 2095014	A	31-05-1992
			DE 69106531	D	16-02-1995
			DE 69106531	T	11-05-1995
			EP 0559780	A	15-09-1993
			WO 9209331	A	11-06-1992
US 5645070	A	08-07-1997	NONE		
US 5712801	A	27-01-1998	NONE		
US 5311874	A	17-05-1994	AU 1488095	A	25-05-1995
			AU 3862893	A	25-11-1993
			CA 2096454	A,C	19-11-1993
			EP 0570896	A	24-11-1993
			JP 6090915	A	05-04-1994
EP 0711531	A	15-05-1996	US 5520191	A	28-05-1996
			JP 8182660	A	16-07-1996
			US 6038469	A	14-03-2000
			US 5819741	A	13-10-1998
US 5792065	A	11-08-1998	NONE		

CORRECTED VERSION

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
17 August 2000 (17.08.2000)

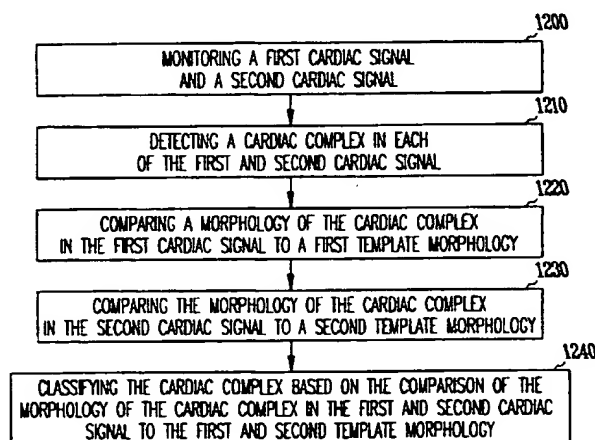
PCT

(10) International Publication Number  
WO 00/47278 A1

- (51) International Patent Classification<sup>7</sup>: A61N 1/37, 1/362 (81) Designated States (*national*): AU, CA, JP.
- (21) International Application Number: PCT/US00/03604 (84) Designated States (*regional*): European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).
- (22) International Filing Date: 11 February 2000 (11.02.2000)
- (25) Filing Language: English Published:  
— with international search report
- (26) Publication Language: English
- (48) Date of publication of this corrected version:  
4 October 2001
- (30) Priority Data:  
09/249,128 12 February 1999 (12.02.1999) US
- (15) Information about Correction:  
see PCT Gazette No. 40/2001 of 4 October 2001, Section II
- (71) Applicant: CARDIAC PACEMAKERS, INC. [US/US];  
4100 Hamline Avenue North, St. Paul, MN 55112 (US).
- (72) Inventors: HSU, William; 8631 Yalta Street N.E., Circle Pines, MN 55014 (US). SMITH, Joseph, Martin; 6343 Waterman Avenue, St. Louis, MO 63130 (US).
- (74) Agent: VIKSNINS, Ann, S.; Schwegman, Lundberg, Woessner & Kluth, P.O. Box 2938, Minneapolis, MN 55402 (US).

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: SYSTEM AND METHOD FOR CLASSIFYING CARDIAC COMPLEXES



(57) Abstract: The present invention provides a system and a method for classifying cardiac complexes based on cardiac information derived from two or more cardiac signals. Two or more cardiac signals containing cardiac complexes are monitored. A cardiac complex in the two or more cardiac signals is isolated in an analysis window. The morphology of the cardiac complex in each of the two or more cardiac signals is then compared to the morphology of a template cardiac complex representing a predetermined cardiac condition. Based on this comparison, the cardiac complex is classified as either belonging or not belonging to the predetermined cardiac condition.

WO 00/47278 A1

## SYSTEM AND METHOD FOR CLASSIFYING CARDIAC COMPLEXES

**Field of the Invention**

This invention relates generally to the field of medical devices and more particularly to a system and method for classifying sensed cardiac complexes.

**Background**

5 Effective, efficient ventricular pumping action depends on proper cardiac function. Proper cardiac function, in turn, relies on the synchronized contractions of the heart at regular intervals. When normal cardiac rhythm is initiated at the sinoatrial node, the heart is said to be in sinus rhythm. However, 10 when the heart experiences irregularities in its coordinated contraction, due to electrophysiological disturbances caused by a disease process or from an electrical disturbance, the heart is denoted to be arrhythmic. The resulting cardiac arrhythmia impairs cardiac efficiency and can be a potential life threatening event.

15 Cardiac arrhythmias occurring in the atrial of the heart are called supraventricular tachyarrhythmias (SVTs). Cardiac arrhythmias occurring in the ventricular region of the heart are called ventricular tachyarrhythmias (VTs). SVTs and VTs are morphologically and physiologically distinct events. VTs take many forms, including ventricular fibrillation and ventricular tachycardia. 20 Ventricular fibrillation is a condition denoted by extremely rapid, nonsynchronous contractions of the ventricles. This condition is fatal unless the heart is returned to sinus rhythm within a few minutes. Ventricular tachycardia are conditions denoted by a rapid heart beat, 150 to 250 beats per minute, that has its origin in some abnormal location within the ventricular myocardium. The 25 abnormal location is typically results from damage to the ventricular myocardium from a myocardial infarction. Ventricular tachycardia can quickly degenerate into ventricular fibrillation.

SVTs also take many forms, including atrial fibrillation and atrial flutter. Both conditions are characterized by rapid uncoordinated contractions of 30 the atria. Besides being hemodynamically inefficient, the rapid contractions of the atria can also adversely effect the ventricular rate. This occurs when the

aberrant contractile impulse in the atria are transmitted to the ventricles. It is then possible for the aberrant atrial signals to induce VTs, such as a ventricular tachycardia.

Implantable cardioverter/defibrillators (ICDs) have been  
5 established as an effective treatment for patients with serious ventricular tachyarrhythmias. ICDs are able to recognize and treat tachyarrhythmias with a variety of tiered therapies. These tiered therapies range from providing antitachycardia pacing or cardioversion energy for treating tachycardia to defibrillation energy for treating ventricular fibrillation. To effectively deliver  
10 these treatments, the ICD must first identify the what type of tachyrrhythmia is occurring in the heart.

Attempts at identifying tachyarrhythmias have included comparing the morphologies of individual cardiac complexes to model or template cardiac complexes. Template cardiac complex morphologies are  
15 created from cardiac complexes sensed from a signal channel electrogram. Once created, the template cardiac complex morphologies are integrated into morphology algorithms programmed into the ICD. As the ICD encounters a tachycardia episode, cardiac complexes sensed on the single channel electrogram are compared to the template cardiac complex morphologies in the morphology  
20 algorithms. Comparing the morphologies of each cardiac complex to the template cardiac complex requires the signals of the two complexes to be positioned over each other. The morphologies of the signals are then analyzed in a time and energy intensive signal shape analysis to determine whether the cardiac complex should be classified as a template cardiac complex.

25 For the reasons stated above, and for other reasons stated below which will become apparent to those skilled in the art upon reading and understanding the present specification, there is a need in the art for providing a reliable system and method for analyzing and classifying cardiac complexes in a more time and energy efficient manner.

### 30 Summary of the Invention

As explained in detail below, the present subject matter utilizes cardiac information from two or more cardiac signals to analyze and classify sensed cardiac complexes in a more time and energy efficient manner. The two

or more cardiac signals are sensed from two or more locations within, or on, the heart of the patient. A cardiac complex sensed using two or more cardiac signals includes the relative time at which the cardiac complex is sensed in each of the two or more cardiac signals. This additional factor allows for a more efficient  
5 comparison to be made between a sensed cardiac complex and a template cardiac complex representing a predetermined cardiac condition. Based on the comparison, the cardiac complex is classified and this information is used to either determine what type of therapy to deliver to a patient or to assess the occurrence of a variety of predetermined cardiac conditions which may be  
10 helpful in providing treatment to the patient.

In one embodiment, the present subject matter provides for the monitoring of two or more cardiac signals representative of a patient's cardiac activity. A cardiac complex is detected in each of the two or more cardiac signals, where the cardiac complex in each of the two or more cardiac signals  
15 represents at least a portion of the heart's cardiac cycle. The morphology of the cardiac complex in each of the two or more cardiac signals is then compared to the morphology of a template cardiac complex. Based on the morphology comparison, the cardiac complex is then classified as either being associated with the template cardiac complex or not being associated with the template  
20 cardiac complex.

In one embodiment, a first signal and a second signal representative of electrical cardiac activity are monitored. As the first signal is being monitored it is analyzed to detect the onset of a tachycardia episode. When a tachycardia episode is detected, individual cardiac complexes in the first  
25 signal and the second signal are detected and windowed for analysis. Predetermined features are then located in the cardiac complex detected in the first signal and in a first normal sinus rhythm representative complex. In one embodiment, the predetermined features include repeatably identifiable complex sections common to the cardiac complex detected in the first signal and the first  
30 NSR representative complex.

The predetermined features located in the first signal and in the first NSR representative complex are then aligned within the analysis window. The cardiac complex detected in the second signal is then compared to a second



NSR representative complex to determine whether the cardiac complex is an arrhythmic cardiac complex. In one embodiment, the morphology of the second NSR representative complex and the morphology of the cardiac complex detected in the second signal to determine whether the cardiac complex is an  
5 arrhythmic complex.

In an alternative embodiment, as a cardiac complexes are detected in the first signal and the second signal they are windowed for analysis. Predetermined features are then located in the cardiac complex detected in the first signal and in a first normal sinus rhythm representative complex. Scalar  
10 values are then generated as a function of the position, or location, of the predetermined features in each of the cardiac signals. The scalar values are then used to create a cardiac vector which represents the cardiac complex.

The cardiac vector is compared to one or more classification vectors, where each of the one or more classification vectors represents a  
15 predetermined cardiac condition. A similarity coefficient is determined for the comparison between the cardiac vector and each of the one or more classification vectors. When a similarity coefficient for the comparison of the cardiac vector and a classification vector exceeds a predetermined threshold, the cardiac complex is classified as the predetermined cardiac condition represented by the  
20 classification vector.

Additionally, the cardiac vector can be aligned with a classification vector prior to comparing the two vectors. In one embodiment, the process of aligning includes adjusting each scalar value in the cardiac vector so one of the element positions of the cardiac vector equals a scalar value in a  
25 corresponding element position in a classification vector.

In an alternative embodiment, as a cardiac complexes are detected in the first signal and the second signal they are windowed for analysis. The morphology of the cardiac complex in the first cardiac signal and the second cardiac signal is then compared to a first template morphology and a second  
30 template morphology, respectively. The cardiac complex is then classified based on the comparison of the morphology of the cardiac complex in the first cardiac signal and the second cardiac signal to the first template morphology and the second template morphology.

These and other features and advantages of the invention will become apparent from the following description of the embodiments of the invention.

### **Brief Description of the Drawings**

Figure 1 is an embodiment of a cardiac complex sensed in two or more  
5 cardiac signals according to the present subject matter;

Figure 2 is an embodiment of cardiac vectors plotted on a three-dimensional Cartesian coordinate system;

Figure 3 is a flow diagram illustrating one embodiment of the present subject matter;

10 Figure 4 is an embodiment of a cardiac complex sensed in two or more cardiac signals according to the present subject matter;

Figure 5 is a schematic view of one embodiment of an implantable medical device with an endocardial lead implanted in a heart from which segments have been removed to show details;

15 Figure 6 is a block diagram of an implantable medical device according to one embodiment of the present subject matter;

Figure 7 is a flow diagram illustrating one embodiment of the present subject matter;

Figure 8 is one embodiment of aligning cardiac complexes according to  
20 the present subject matter;

Figure 9 is one embodiment of aligning cardiac complexes according to the present subject matter;

Figure 10 is a flow diagram illustrating one embodiment of the present subject matter;

25 Figure 11 is a flow diagram illustrating one embodiment of the present subject matter; and

Figure 12 is a flow diagram illustrating one embodiment of the present subject matter.

### **Detailed Description**

30 In the following detailed description, reference is made to the accompanying drawings which form a part hereof and in which is shown by way of illustration specific embodiments in which the invention may be practiced. These embodiments are described in sufficient detail to enable those skilled in

the art to practice and use the invention, and it is to be understood that other embodiments may be utilized and that electrical, logical, and structural changes may be made without departing from the spirit and scope of the present invention. The following detailed description is, therefore, not to be taken in a limiting sense and the scope of the present invention is defined by the appended claims and their equivalents.

The embodiments of the present subject matter illustrated herein are described as being included in an implantable cardiac defibrillator, which may include numerous pacing modes known in the art and an external medical device programmer. In one embodiment, the implantable cardiac defibrillator is a single chamber defibrillator. In an alternative embodiment, the implantable cardiac defibrillator is a dual chamber defibrillator. Examples of both single and dual chamber implantable cardiac defibrillators are known in the art. However, the present medical system can also be implemented in an external cardioverter/monitor system as are known in the art. Also, the present medical system can also be implemented in an implantable atrial cardioverter-defibrillator, which may include numerous pacing modes known in the art. Furthermore, although the present system is described in conjunction with an implantable cardiac defibrillator having a microprocessor based architecture, it will be understood that the implantable cardiac defibrillator (or other implanted device) may be implemented in any logic based custom integrated circuit architecture, if desired.

With respect to the present subject matter, accurate classification of sensed cardiac complexes is important to an overall diagnosis and treatment of a patient's cardiac condition. In an effort to classify and categorize sensed cardiac complexes, the morphology of individual cardiac complexes is compared to template cardiac complexes. The template cardiac complexes are derived from cardiac complexes sensed during arrhythmic or non-arrhythmic cardiac episodes.

The cardiac signals used in creating the template cardiac complex and classifying sensed cardiac complexes have typically been detected using a signal channel electrogram. Single channel electrograms, however, limit the amount of cardiac information available to use in classifying cardiac complexes. In contrast, one unique aspect of the present subject matter is that cardiac

information from two or more cardiac channels is used to classify sensed cardiac complexes. Using two or more cardiac channels provides cardiac information from two or more locations within, or on, the heart of the patient. By utilizing multiple cardiac channels, cardiac information (e.g., sensed cardiac complexes) from the two or more cardiac regions and/or locations provide a larger overall and more complete "view" of the sensed cardiac complexes.

The present subject matter uses two or more electrogram channels in a process of analyzing and classifying cardiac complexes. Each electrogram channel is used to sense a cardiac signal, where the cardiac signal includes cardiac complexes representative of at least a portion of a cardiac cycle. By way of example, and not by way of limitation, portions of the cardiac cycle sensed can include, but are not limited to, P-waves, QRS-cardiac complexes, and R-waves. Other portions of the cardiac cycle, including sensed signals of the entire cardiac complex are considered useful and within the scope of the present subject matter.

In one embodiment, the present subject matter provides for two or more electrogram channels to simultaneously record cardiac complexes as they occur in the heart. As the cardiac complexes occur, each electrogram channel detects cardiac complexes representing portions of the cardiac cycle. The two or more electrogram channels are being sensed from sensors in or on different cardiac locations. While sensors may detect the electrical activity during the same portion of the cardiac cycle, having the sensors in different cardiac locations allows for cardiac information about the same cardiac complex to be gathered from a different "view" of the cardiac cycle. Each cardiac complex sensed with the two or more electrogram channels is placed in an analysis window, where the cardiac complex is isolated for analysis. In one embodiment, each cardiac complex is windowed by isolating and plotting the portions of the simultaneously sensed cardiac complex in the two or more electrogram channels as they occurred in time.

Figure 1 shows one embodiment of a windowed cardiac complex 100. In the present example, the windowed cardiac complex 100 has a first cardiac channel 104, a second cardiac channel 108 and a third cardiac channel 112. Cardiac complexes are sensed over the first cardiac channel 104, the

second cardiac channel 108 and the third cardiac channel 112, where each cardiac channel may sense a different portion of the cardiac complex (e.g., R-wave, QRS-cardiac complex, P-wave, etc.). In the present example, the windowed cardiac complex 100 has three views of a cardiac complex as sensed  
5 over the three cardiac channels. A first cardiac complex 116 is shown in cardiac signal sensed in the first cardiac channel 104. A second cardiac complex 120 is shown in cardiac signal sensed in the second cardiac channel 108. Finally, a third cardiac complex 123 is shown in cardiac signal sensed in the third cardiac channel 112. The first, second and third cardiac complex 116, 120 and 124 are  
10 representative of at least a portion of a single cardiac cycle. In one embodiment, the first, second and third cardiac complex 116, 120 and 124 are snapshots of the single cardiac cycle taken either at different locations within or on the heart and/or taken using different electrode configurations (e.g., far-field, near-field).

Cardiac information is derived from the windowed cardiac  
15 complexes. In one embodiment, information derived from the windowed cardiac complexes includes values derived or taken from one or more predetermined features on the cardiac complex sensed in each of the two or more cardiac channels. By way of example, and not by limitation, predetermined features of the cardiac complexes that are useful in deriving information include a  
20 maximum deflection of the cardiac complex, a beginning of a cardiac complex as indicated by a predetermined deviation of the cardiac signal from a baseline signal, an ending of a cardiac complex as indicated by a return of the first cardiac signal to a baseline signal and a fiducial point (the point of greatest slope along the cardiac complex signal). Other features of the cardiac complex signal are  
25 also useful for deriving information. In one embodiment, the selection criteria for these additional features of a cardiac complex is that the feature be a repeatably identifiable portion of the cardiac complex. In one embodiment, the features are selectively programmed into the medical device system.

Figure 1 shows several examples of predetermined features of the  
30 sensed cardiac complex that are useful in deriving information. In one embodiment, a beginning of the first, second and third cardiac complex (116, 120 and 124) sensed in the first, second and third cardiac channel (104, 108 and 112), respectively, is generally shown at 128. A maximum deflection point of

the first, second and third cardiac complex (116, 120 and 124) is shown generally at 132. Finally, an ending point of the first, second and third cardiac complex (116, 120 and 124) is shown generally at 136.

In one embodiment, the cardiac complexes sensed in the two or  
5 more cardiac channels are windowed with each of the signals of the cardiac complexes represented as a voltage at a function of time. Figure 1 shows an example of the first, second and third cardiac complex (116, 120 and 124) sensed in the first, second and third cardiac channel (104, 108 and 112) being plotted as voltage as a function of time. Once the cardiac complex sensed in the two or  
10 more cardiac channels is represented in this fashion, information can be derived from the specific features of the cardiac complexes.

In one embodiment, the information derived from the cardiac complexes in each of the cardiac channels is the time the repeatably identifiable feature of the cardiac complex occurred. Alternatively, the information derived  
15 is a time difference between pairs of repeatably identifiable features on a cardiac complex sensed in one of the two or more electrogram channels. In one embodiment, a first time difference 140 is between the beginning 128 of the first cardiac complex 116 and the end 136 of the first cardiac complex. In an additional embodiment, the information derived is a time difference between  
20 pairs of repeatably identifiable features on two different cardiac complexes sensed in two electrogram channels. In a further embodiment, the information derived is a combination of the time difference between pairs of repeatably identifiable features on two different cardiac complexes sensed in two electrogram channels and the time differences from pairs of repeatably  
25 identifiable features on a cardiac complex sensed in one of the two or more electrogram channels.

Information from multiple cardiac channels can then be used to represent the cardiac complex. In one embodiment, the cardiac complex sensed in multiple cardiac channels can be numerically represented. One way of  
30 numerically representing the cardiac complex is to use scalar values derived from the cardiac signals of the cardiac complex. In one embodiment, the scalar values derived from the cardiac signals of the cardiac complex are the times repeatably identifiable features of the cardiac complex occur. Alternatively, time

differences between the repeatably identifiable features, as previously described, are used to derive the scalar values. In an additional embodiment, the scalar values can be derived from a magnitude of the position of the predetermined feature for each of the two or more cardiac signals. In one embodiment, the  
5 magnitude of the position of the predetermined feature is the voltage measurement of the maximum deflection position along the cardiac signal.

The values derived for a cardiac complex are then used to create an "N" dimensional cardiac complex vector. In one embodiment, the cardiac complex vector has the form:  $A = [A1, A2, A3, \dots An]$ , where each of the  
10 values  $A1 - An$  represent scalar values derived from the repeatably identifiable features of the cardiac complex. The cardiac complex vector represents the cardiac complex, and is used to identify and classify the cardiac complex.

Once the cardiac complex vector has been derived from cardiac complex information taken from the two or more cardiac channels, the cardiac  
15 complex vector is compared to one or more classification vectors. In one embodiment, a classification vector represent a typical cardiac complex of a specific cardiac arrhythmia or cardiac state. For example, a classification vector can represent a ventricular tachycardia (VT) complex, where there can be one or more classification vectors to represent one or more different manifestations of  
20 ventricular tachycardia complexes. Additionally, classification vectors can represent supraventricular tachycardia (SVT) complexes, premature ventricular contraction (PVC) complexes, complexes indicating ischemic events, and any predefined representation of a cardiac complex.

In one embodiment, classification vectors are predefined  
25 classification vectors derived from cardiac complexes sensed over two or more cardiac channels for a population of patients. In one embodiment, the population of patients chosen to determine a classification vector display or manifest the cardiac condition of interest (e.g., VT, SVT, PVC). Cardiac complexes of the cardiac conditions of interest are recorded over two or more cardiac channels  
30 from the patients. Using repeatably identifiable features of the multiple cardiac signals representing each cardiac complex, classification vectors for a cardiac condition are developed. In one embodiment, cardiac complexes are sensed and recorded during Holter monitoring.

In one embodiment, the classification vectors has the form:  $C = [C1, C2, C3, \dots Cn]$ , where each of the values  $C1 - Cn$  represent scalar values derived from the repeatably identifiable features of the cardiac complexes. In one embodiment, each of the values  $C1 - Cn$  are average values derived from  
5 repeatably identifiable features of the cardiac complexes for the patient population. In an alternative embodiment, each of the values  $C1 - Cn$  are median values derived from repeatably identifiable features of the cardiac complexes for the patient population. One or more of the predetermined classification vectors can then be used in the implantable medical device to classify sensed cardiac  
10 complexes.

In an alternative embodiment, the classification vectors are derived from cardiac complexes sensed from the patient. In one embodiment, two or more cardiac signals are recorded from the patient for a predetermined length of time. In one embodiment, sensing and recording the cardiac complexes is  
15 accomplished through Holter monitoring. From the recorded cardiac complexes, classification vectors are developed as previously discussed. In an additional embodiment, classification vectors represent predefined deviations between two or more repeatably identifiable features of a cardiac complex in the two or more cardiac signals. In this embodiment, the classification vector is not representing  
20 a particular cardiac condition (e.g., VT, SVT, PVC complex) but rather is representative of a very specific cardiac condition or occurrence that the physician want to pay particular attention to. By developing and programming this type of classification vector, the physician can determine how may cardiac complexes of this particular type are occurring.

25 In an alternative embodiment, classification vectors are created after the medical device system has been implanted into the patient. One way to create patient specific classification vectors is to derive scalar values from predetermined features of the cardiac complexes sensed in the two or more cardiac channels. As the scalar values are determined from the first sensed  
30 cardiac complex, the medical device system determines the cardiac complex vector. The cardiac complex vector for the first cardiac complex is then classified as a first class of sensed cardiac complexes. As the second cardiac complex is sensed, the medical device system determines the cardiac complex



vector A for the second cardiac complex. The cardiac complex vector A for the second cardiac complex is then compared to the cardiac complex vector A for the first cardiac complex to determine whether the second cardiac complex should be classified in the first class of sensed cardiac complexes or classified in  
 5 a second class of sensed cardiac complexes.

In one embodiment, determining whether a cardiac complex should be grouped with one or more classified cardiac complexes is accomplished through a process of comparing the complex vector A of the cardiac complex to be classified with the complex vector A of the cardiac complex that founded the  
 10 class of cardiac complexes. Figure 2 shows an embodiment of cardiac complex classes. Figure 2 shows cardiac complexes being plotted in a Cartesian coordinate system with three-dimensions 200. Cardiac vectors plotted in 200 have three values  $A=[A1, A2, A3]$ . As the first cardiac complex of a patient is sensed, the cardiac vector is determined. As previously discussed, the first  
 15 cardiac complex becomes the first class of sensed cardiac complexes. The cardiac vector of the first cardiac complex is shown at 204.

The cardiac vector of the first cardiac complex not only establishes the first class of sensed cardiac complexes, but it is also used to determine whether subsequently sensed cardiac complexes should be included in the first  
 20 class of sensed cardiac complexes or excluded to join another class of sensed cardiac complex or form a new class of sensed cardiac complexes. In one embodiment, to determine whether a second cardiac complex is classified with the first class of sensed cardiac complexes the cardiac vector of the second cardiac complex is compared to the cardiac vector of the first cardiac complex.

25 In one embodiment, a mean square error calculation is used to determine if the scalar values of the cardiac vectors are sufficiently close, or within a region, or "neighborhood", to classify the second cardiac complex in the first class of cardiac complexes. In one embodiment, the mean square error is represented as  $\sum (A_{i(n \text{ class})} - A_i)^2 \leq T$ , where  $A_{i(n \text{ class})}$  represents the ith scalar  
 30 value ( $A1 - A_n$ ) of the n class (first class, second class, third class, . . . , nth class) of sensed cardiac complexes and T is a predetermined threshold value. In one embodiment, the predetermined threshold value T defines the region around the cardiac complex representing each of the classes of sensed cardiac complexes.

Figure 2 shows one example of a first region 208 surrounding the cardiac vector of the first cardiac complex 204. As previously discussed, after the second cardiac complex is sensed, the cardiac vector representing the second cardiac complex is compared to the cardiac vector representing the first class of cardiac complexes, which in this case is the first cardiac complex 204. In one embodiment, if the cardiac vector representing the second cardiac complex falls on or within the first region 208, the second cardiac complex is classified as part of the first class of cardiac complexes.

In an alternative embodiment, if the cardiac vector representing the second cardiac complex falls outside the first region 208, the second cardiac complex is used to create a second class of cardiac complexes. In one embodiment, the cardiac vector of the second cardiac complex is shown at 212. A second region 216 surrounds the second cardiac complex 212. As previously discussed, the size of the second region 216 surrounding the second cardiac complex is dependent on the predetermined threshold value T.

As a subsequent cardiac complex is sensed a cardiac vector representing the cardiac complex is determined. The cardiac vector is then compared to each established class of cardiac complex. If the cardiac vector is found to fall within the region around a cardiac vector representing a class of cardiac complexes, the cardiac vector is classified with that class of cardiac complexes. So, if the cardiac complex is found to fall into the region representing a third class of cardiac complexes, the cardiac complex would be classified and counted with the third class of cardiac complexes. If, however, the cardiac complex does not fall into a region surrounding one or more classes of cardiac complexes, the cardiac vector of the cardiac complex is used to create a new class (an "nth" cardiac class) of cardiac complexes.

The cardiac vectors that establish a class of cardiac complexes are electronically stored in the implantable medical device. In addition to electronically storing the cardiac vectors, the medical device system also stores at least the electrocardiogram signal of the cardiac complex that established the class of cardiac complexes. In an additional embodiment, values for the cardiac vectors classified in each of the classes of cardiac complexes are also electronically stored in the medical device system. In one embodiment, it is

possible that a cardiac complex is classified into two or more classes of cardiac complexes. In one embodiment, the cardiac complex falling into two or more classes of cardiac complexes will be reported in each class of cardiac complexes. In an alternative embodiment, cardiac complexes falling into two or more classes  
5 will classified and reported in the class that they were originally classified.

The patient cardiac complexes are sensed and classified by the implantable medical device for a predetermined period of time. In one embodiment, the predetermined period of time over which cardiac complexes are sensed and used to create the classes of cardiac complexes is programmed by the  
10 patient's attending physician. In one embodiment, cardiac complexes are sensed over a continuous period of time. Alternatively, the implantable medical device is programmed to classify sense cardiac complexes during predetermined time segments over the course of 24 hours. Additionally, the implantable medical device is programmed to classify sense cardiac complexes only after the cardiac  
15 rate (ventricular and/or atrial rate) has reached or exceeded are predetermined threshold (e.g., known cardiac rate threshold indicative of ventricular tachycardia, atrial tachycardia, etc.).

Upon a follow-up visit to the patient's physician, the cardiac information contained in the implantable medical device is down-loaded to a  
20 medical device programmer unit. In one embodiment, information relating to cardiac complexes used to establish classes of cardiac complexes is down-loaded and displayed on a display screen of the medical device programmer. Additionally, the number of cardiac complexes classified into each of the classes of cardiac complexes can be displayed. Electrocardiogram signals representative  
25 of each class of cardiac complex can also be displayed. The physician then uses the classes of cardiac complexes to define or designate classification vectors which are subsequently used to identify cardiac complexes and classify a cardiac arrhythmia that the patient may experience.

Figure 3 shows one embodiment of a method of the present subject  
30 matter. At 300, two or more cardiac signals representative of electrical cardiac activity are monitored. The cardiac signals are monitored to detect cardiac complexes occurring in the two or more cardiac signals. In one embodiment, an implantable medical device, such as an implantable cardioverter defibrillator, is

used to detect cardiac complexes in the two or more cardiac signals. In one embodiment, the implantable medical device has two or more cardiac electrodes which allow for near-field and/or far-field cardiac signals to be sensed from a heart.

5           At 310, the cardiac complex present in the two or more cardiac signals is isolated in an analysis window (or "windowed" for analysis). As previously discussed, windowing isolates a section, or portion, of the two or more cardiac signals which each contain a view of the cardiac complex that is being classified. After the cardiac signals containing the cardiac complex have  
10   been isolated, at least one predetermined feature is located in the cardiac complex present in each of the two or more cardiac signals.

          Once the cardiac signals containing the cardiac complex have been windowed, scalar values from predetermined features of the cardiac complex are generated. In one embodiment, the scalar values are generated as a function of  
15   the position of the predetermined feature, or features, on each of the two or more cardiac signals. The scalar values are then used to create a cardiac vector, where the cardiac vector represents the cardiac complex.

          Figure 4 shows one embodiment of cardiac complexes of a cardiac cycle windowed for analysis and classification. A first cardiac complex 400 is  
20   present in the first cardiac signal 404 and a second cardiac complex 408 is present in a second cardiac signal 412. As previously discussed, the two or more cardiac signals are sensed simultaneously from the heart, and so the first cardiac complex 400 and the second cardiac complex 408 are representative of portions of a complete cardiac cycle occurring in the heart.

25           Predetermined features of the cardiac complex in each cardiac signal are used to derive a cardiac vector. In the present example, the cardiac vector is programmed to have four values, such that  $A=[A1, A2, A3, A4]$ . Each of the values A1 - A4 represent scalar values derived from the repeatably identifiable features of the cardiac complex. In one embodiment, A1 is  
30   programmed to be the beginning time 416 of the first cardiac complex 400, A2 is programmed to be the time of the maximum deflection point 420 of the first cardiac complex 400, A3 is programmed to be the time difference 424 between the time of the maximum deflection point 420 and the time of the maximum

deflection point 428 of the second cardiac complex 408, and A4 is programmed to be the beginning time 432 of the second cardiac complex 408.

Referring again to Figure 3, after a cardiac vector has been determined for the cardiac complex, the cardiac vector is compared to one or more classification vectors at 330. In one embodiment, the one or more classification vectors represents a predetermined cardiac condition. For example, the predetermined cardiac conditions can include, but are not limited to, ventricular and supraventricular tachycardia, PVCs, ischemia, or other predetermined cardiac conditions designated by a physician. In addition, the cardiac vector has the same vector dimension as the classification vectors. In one embodiment, the scalar values making up the cardiac vector are determined from the same relative predetermined features of the cardiac signals sensed in the same general cardiac location using the same general cardiac electrode configuration.

In one embodiment, the cardiac vector is compared to the classification vectors to determine whether the cardiac vector similar enough to one or more classification vectors to classify the cardiac complex. In one embodiment, a similarity coefficient is determined from each comparison of the cardiac vector and the one or more classification vectors. Based on this similarity coefficient, the cardiac complex is classified as the predetermined cardiac condition when the cardiac complex similarity coefficient exceed a predetermined threshold. In one embodiment, a mean square error is used to determine the similarity coefficient. In one embodiment, the mean square error value is represented as  $\sum (A_i - C_i)^2 \leq X$ , where  $A_i$  represents the  $i$ th scalar value ( $A_1 - A_n$ ) of the cardiac vector,  $C_i$  represents the  $i$ th scalar value ( $C_1 - C_n$ ) of the classification vector and  $X$  is a predetermined threshold value. In one embodiment, the predetermined threshold value  $X$  defines the region or a neighborhood around the classification vector which is deemed to be sufficiently close to permit classifying the cardiac complex represented by the cardiac vector as a general class of cardiac complexes represented by the classification vector. Based on the comparison, the cardiac complex is classified at 340 as being a member of the group represented by one or more classification vectors if possible.

In an additional embodiment, prior to comparing the cardiac vector to the classification vectors, the cardiac vector is aligned, or coordinated with, each of the classification vectors. In one embodiment, the cardiac vector and the classification vectors include element positions (A1 and C1 are in the first  
5 element position, A2 and C2 are in the second element position, etc.) which are occupied by the scalar values. The cardiac vector and a classification vector are aligned around the scalar values in the same element position (i.e., a coordinating element position) in both the cardiac vector and the classification vector.

10 In one embodiment, the process of aligning the cardiac vector and the classification vector involves adjusting each scalar value of the cardiac vector so one of the element positions of the cardiac vector equals a scalar value in a corresponding element position in a classification vector. So, when the scalar values in the vectors are the time of occurrence of features in different channels,  
15 the vectors are aligned by add or subtract an appropriate numerical value to all the elements of the cardiac vector (e.g., the scalar values in the cardiac vector) so that the scalar value in the coordinating element position of the cardiac vector has the same numerical value as the coordinating element position of the classification vector.

20 In one embodiment of aligning a cardiac vector and a classification vector, a cardiac complex is sensed two or more cardiac channels, from which a cardiac vector  $A=[A1, A2, A3, A4]$  is determined. In this embodiment, the elements of the vector are times at which the repeatably identifiable features of the cardiac complex occurred in the two or more cardiac channels. One or more  
25 classification vectors are provided having the general form  $C=[C1, C2, C3, C4]$ . In one embodiment, the cardiac vector is aligned, or coordinated, around the same element position (the coordinating element) with each classification vector the cardiac vector is compared with. In one embodiment, the coordinating element is the first position in the cardiac vector and the classifying vector, A1 and C1. A numerical value Y is added to, or subtracted from, the value of A1 so  
30 that A1 equals C1. So,  $A1 + Y = C1$ , where Y can have either a positive or a negative numerical value. In addition to modifying the value of A1 with Y, Y is also added to the remaining elements of the cardiac vector. So, a cardiac vector

aligned with a classification vector has the form  $A_a = [A1+Y, A2+Y, A3+Y, A4+Y]$ , where  $A1+Y = C1$  of the classification vector  $C = [C1, C2, C3, C4]$ . After the cardiac vector has been aligned with the classification vector, the elements of the vectors, excluding the coordinating elements, are compared.

- 5 This means that for the present example, the classification vector  $A_a = [A2+Y, A3+Y, A4+Y]$  would be compared to the classification vector  $C = [C2, C3, C4]$ . Finally, the cardiac vector can be aligned with a classification vector around any element (e.g.,  $A1/C1, A2/C2$ , etc.) in the pair of vectors.

- As previously discussed, the present subject matter uses two or  
10 more electrogram channels in a process of analyzing and classifying cardiac complexes. In one embodiment, a first cardiac signal and a second cardiac signal are sensed over a first electrogram channel and a second electrogram channel, respectively. During a tachycardia episode, a cardiac complex is detected in the first cardiac signal and the second cardiac signal. The morphology of the first  
15 cardiac signal and the second cardiac signal representing the cardiac complex can then be compared to template cardiac complexes. Based on this comparison, the cardiac complex can be classified as being representative of one or more predetermined cardiac rhythm states. Predetermined cardiac rhythm states can include, but are not limited to, arrhythmic or non-arrhythmic, normal sinus  
20 rhythm (NSR), ventricular tachycardia and/or supraventricular tachycardia cardiac rhythm states.

- In an additional embodiment, the process of comparing the morphology of the cardiac complex to a template cardiac complex includes the act of aligning, or coordinating, the cardiac complex sensed in a first cardiac  
25 signal of the two or more cardiac signals with a template cardiac complex having been derived from cardiac complexes sensed in the first cardiac signal. Alternatively, the morphology of the cardiac complex sensed in the two or more cardiac channels is compared to the morphology of the template cardiac complex which was derived from cardiac complexes sensed in the two or more cardiac  
30 channels.

In one embodiment, a first cardiac signal and a second cardiac signal are sensed over a first electrogram channel and a second electrogram channel, respectively. During a tachycardia episode, a cardiac complex is

detected in the first cardiac signal and the second cardiac signal. In one embodiment, the cardiac complex detected in the first cardiac signal is aligned, or coordinated, with a first normal sinus rhythm (NSR) representative complex. In one embodiment, the first NSR representative complex is the template cardiac complex which, in the present embodiment, was derived from normal sinus rhythm cardiac complexes detected in the first cardiac signal.

Once the cardiac complex from the first cardiac signal has been aligned with the first NSR representative complex, the cardiac complex from the second cardiac signal is morphologically compared to the second NSR representative complex. In the present embodiment, this comparison is then used to classify the cardiac complex as either a complex representative of an arrhythmic episode or of a non-arrhythmic episode.

Through the process of first aligning the cardiac complex sensed in the first cardiac signal with the first NSR representative complex, the comparison of the cardiac complex as sensed in the second cardiac signal to the second NSR representative complex not only uses the relative morphologies of the cardiac complexes in classifying the cardiac complex, but also takes into consideration the relative time the cardiac complex detected in the first cardiac signal occurred with respect to the cardiac complex detected in the second cardiac signal. The relative time between the sensed cardiac complex in the first cardiac signal and the second cardiac signal helps to further accentuates morphological differences in the cardiac complex and template cardiac complex.

Referring now to Figure 5 of the drawings, there is shown one embodiment of a medical device system suitable for implementing the present subject matter. By way of example only, and not by limitation, the medical device system includes an implantable cardiac defibrillator 500 electrically and physically coupled to at least one catheter 502. In one embodiment, the catheter 502 is an intracardiac catheter which includes at least a first cardiac electrode and a second cardiac electrode.

The catheter 502 is implanted in a human body 504 with portions of the catheter 502 inserted into a heart 506 to detect and analyze electric cardiac signals produced by the heart 506 and to provide electrical energy to the heart



506 under certain predetermined conditions to treat cardiac arrhythmias, including ventricular fibrillation, of the heart 506.

In one embodiment, the catheter 502 is an endocardial lead adapted to be releasably attached to the cardiac defibrillator 500. The catheter 502 has an elongate body with a proximal end 508 and a distal end 510, and includes at least a first cardiac electrode and a second cardiac electrode. In one embodiment, the catheter 502 has a pacing electrode 512 located at, or adjacent, the distal end 510 of the catheter 502. Additional pacing electrodes can also be included on the catheter 502 to allow for bipolar sensing and pacing with the pacing electrode 512. In addition, other pacing and sensing electrode configurations are also possible. The catheter 502 also includes one or more defibrillation electrodes. In one embodiment, the catheter 502 has a first defibrillation electrode 514 and a second defibrillation electrode 516, where the defibrillation electrodes have a coil construction as is known.

In addition to the catheter configuration shown in Figure 5, it is considered within the scope of the present subject matter that additional catheters positioned in or around the ventricular and/or the atrial chambers can be added to the cardiac defibrillator 500 to allow for additional cardiac signals to be sensed (e.g., two or more cardiac signals). Thus, it would be possible to sense cardiac signals from any combination or subcombination of ventricular, right ventricular, left ventricular, atrial, right atria and/or left atria locations. These signals can include, but are not limited to, far-field and/or near-field cardiac signals.

Referring now to Figure 6, there is shown an embodiment of a block diagram of a cardiac defibrillator 500. The cardiac defibrillator 500 includes control system circuitry 600 for receiving cardiac signals from a heart 506 and delivering electrical energy to the heart 506. The control system circuitry 600 includes a sensing system 602 attached to at least one catheter. The sensing system 602 includes terminals labeled with reference numbers 604, 608, and 612 for connection to electrodes attached to the surface of the catheter 502. In one embodiment, the pacing electrode 512 is electrically connected to terminal 604 and to the control system circuitry 600 through an electrically insulated conductor provided within the elongate body of the catheter 502. The first defibrillation electrode 514 and the second defibrillation electrode 516 are

connected to terminals 608 and 612, respectively, and to the control system circuitry 600 through electrically insulated conductors provided within the elongate body of the catheter 502.

In one embodiment, the control system circuitry 600 of the cardiac defibrillator 500 is encased and hermetically sealed in a housing 530 suitable for  
5 implanting in a human body as are known in the art. A connector block 532 (Figure 5) is additionally attached to the housing 530 of the cardiac defibrillator 500 to allow for the physical and the electrical attachment of the catheter 502 and the electrodes to the cardiac defibrillator 500 and the encased control system  
10 circuitry 600.

In one embodiment, the control system circuitry 600 of the cardiac defibrillator 500 is a programmable microprocessor-based system, with a microprocessor 616 and a memory circuit 620 which contains parameters for various pacing, defibrillation, and sensing modes and stores data indicative of  
15 cardiac signals received by the control system circuitry 600. A transmitter circuit 624 is additionally coupled to the control system circuitry 600 and the memory circuit 620 to allow the cardiac defibrillator 500 to communicate with and receive programming instructions and transmit data to and from a programmer unit 228 as is known in the art. In one embodiment, the transmitter  
20 circuit 624 and the programmer unit 628 use a wire loop antenna 632 and a radio frequency telemetric link, as is known in the art, to receive and transmit signals and data to and from the programmer unit 628 and the control system circuitry 600. In this manner, programming commands or instructions are transferred to the microprocessor 616 of the cardiac defibrillator 500 after implant, and stored  
25 cardiac data pertaining to sensed arrhythmic episodes within the heart 506 and subsequent therapy, or therapies, applied to correct the sensed arrhythmic event are transferred to the programmer unit 628 from the cardiac defibrillator 500.

In the present embodiment, the medical device system senses at least a first signal and a second signal, both of which are representative of  
30 electrical cardiac activity. The first signal and the second signal each contain cardiac complexes which represent at least a portion of the cardiac cycle. Based on the embodiment shown in Figure 5, the first signal is a rate signal sensed within the right ventricle chamber of the heart and the second signal is a

morphology signal sensed across at least a portion of the ventricular region of the heart. In an alternative embodiment, the first and second signals can be rate and morphology signals sensed in a supraventricular region of the heart.

Alternatively, cardiac electrodes and/or catheters can be provided to allow for the  
5 first signal to be a morphology signal and the second signal to be a rate signal.

In the embodiment shown in Figure 5, the pacing electrode 512 is included in a near-field channel which senses near-field signals or rate-signals of the heart 506. The near-field sensing channel includes the pacing electrode 512 which is coupled to a sense amplifier 630 within the sensing system 602. In one  
10 embodiment, the housing 530 of the cardiac defibrillator 500 is coupled to the sense amplifier 630 at 634 to allow for unipolar cardiac rate sensing between the pacing electrode 512 and the housing 530 of the cardiac defibrillator 500. In an alternative embodiment, the cardiac rate signal is sensed using pacing electrode 512 and the first defibrillation electrode 514.

15 The output of the sense amplifier 630 is shown connected to an R-wave detector 636. The R-wave detector 636 serves to sense and amplify cardiac signals, including cardiac complexes, sensed from the heart, and apply signals indicative thereof to a signal feature comparison circuit 638. The signal feature comparison circuit 638 is coupled to the microprocessor 616. Among other  
20 things, microprocessor 616 responds to signals from the R-wave detector 636 by providing pacing signals to a pace output circuit 640, as needed according to the programmed pacing mode. In one embodiment, the pace output circuit 640 provides output pacing signals to terminals 604 and 634, which connect to the pacing electrode 512 and the housing 530 of the cardiac defibrillator 500, for  
25 cardiac pacing.

Referring again to the embodiment in Figure 5, far-field or morphology signals are sensed through the first defibrillation electrode 514 and the second defibrillation electrode 516. The first defibrillation electrode 514 and the second defibrillation electrode 516 are used in a far-field sensing channel,  
30 where the first defibrillation electrode 514 and the second defibrillation electrode 516 are coupled to a sense amplifier 644 to sense far-field signals, which include cardiac complexes, from the heart. In an alternative embodiment, far-field signals are sensed between the first defibrillation electrode 514, the second

defibrillation electrode 516 and the housing 530. The output of the sense amplifier 644 is coupled to a morphology analyzer circuit 648.

The morphology analyzer circuit 648 receives and processes the cardiac complexes detected within the cardiac signals. In one embodiment, the morphology analyzer circuit 648 receives cardiac signals, including cardiac complexes representative of the cardiac cycle from the sensing system. Cardiac complexes analyzed by the morphology analyzer circuit 648 can include detected P-waves, QRS-complexes, and R-waves. In one embodiment, the morphology analyzer circuit 648 includes an analog filter for filtering cardiac signal noise sensed by the electrodes. The cardiac signals are then bandlimited before arriving at an analog-to-digital filter which converts the analog signals into digital signals suitable for processing. In an alternative embodiment, the cardiac signals are filtered through an analog peak detector to extract the maximum and minimum cardiac signal values for each sensed cardiac complex.

In processing sensed cardiac complexes, the morphology analyzer circuit 648 windows a cardiac complex sensed in two or more cardiac signals. In one embodiment, the morphology analyzer circuit 648 locates and extracts information from one or more predetermined features of sensed cardiac complexes. As previously discussed, the type of information extracted by the morphology analyzer circuit 648 can include the time of occurrence of a predetermined feature and the amplitude value of a predetermined feature. In one embodiment, the predetermined features include repeatably identifiable portions of cardiac complexes which are repeatably identifiable in subsequent cardiac complexes. For example, features include a maximum deflection of the cardiac complex, a beginning of a cardiac complex as indicated by a predetermined deviation of the cardiac signal from a baseline signal, and an ending of a cardiac complex as indicated by a return of the first cardiac signal to a baseline signal. In one embodiment, the features are selectively programmed into the medical device system.

A template generator circuit 650 is coupled to the sensing system 602. The template generator circuit 650 receives information from the morphology analyzer 648. In one embodiment, the information received from the morphology analyzer 648 includes the information extracted from the two or

more cardiac signals by the morphology analyzer circuit 648. In one embodiment, the template generator circuit 650 creates the numerical representation of sensed cardiac complexes. The template generator circuit 650 then creates the "N" dimensional cardiac complex vector from these values as  
5 previously described. In addition, the template generator circuit 650 is also used to create the one or more classification vectors from a patient's own cardiac complexes as previously described.

In an alternative embodiment, the template generator circuit 650 receives at least the first signal and the second signal sensed from the heart 506.  
10 In one embodiment, the template generator circuit 650 determines a first normal sinus rhythm (NSR) representative complex and a second NSR representative complex from a plurality cardiac complexes sensed during normal sinus rhythm. In one embodiment, the first NSR representative complex and the second NSR representative complex are averages of cardiac complexes sensed in the first  
15 signal and the second signal during a patient's normal sinus rhythm. In an alternative embodiment, the first NSR representative complex and the second NSR representative complex are median values of the cardiac complexes sensed in the first signal and the second signal during a patient's normal sinus rhythm.

After the cardiac signals and information relating to the cardiac  
20 complexes in the cardiac signals have been processed by the morphology analyzer circuit 648 and the template generator circuit 650, the signals are received by a signal feature comparison circuit 638. The signal feature comparison circuit 638 uses information contained in the cardiac signals to analyze and classify sensed cardiac complexes.

25 In one embodiment, the signal feature comparison circuit 638 uses the one or more classification vectors which are stored in memory 620. The signal feature comparison circuit 638 compares the cardiac complex vector to the one or more classification vectors, as previously described, to classify the cardiac complex represented by the cardiac complex vector. In an additional  
30 embodiment, the signal feature comparison circuit 638 can also align the cardiac vectors with classification vectors prior to comparing the vectors when programmed to perform this function.

In an alternative embodiment, as cardiac complexes are sensed using the first cardiac signal and the second cardiac signal, the signal feature comparison circuit 638 aligns the predetermined feature in the cardiac complex monitored in the first signal with the predetermined feature on the first NSR representative complex. Once the predetermined features in the cardiac complex from the first signal is aligned with the corresponding predetermined feature in the first NSR representative complex, the morphology analyzer circuit 648 compares the cardiac complex monitored in the second signal to the second NSR representative complex to determine whether the cardiac complex is an arrhythmic complex. In one embodiment, the morphology analyzer circuit 648 compares the morphology of the cardiac complex monitored in the second signal to the second NSR representative complex to determine whether the cardiac complex is an arrhythmic complex.

In an alternative embodiment, the morphology analyzer 648 can also compare the morphology of a cardiac complex sensed in two or more cardiac channels to one or more template cardiac complexes to classify the cardiac complex. In one embodiment, the template cardiac complexes are determined from cardiac complexes sensed in the two or more cardiac channels which are subsequently used to sense cardiac complexes to be classified. Alternatively, the template cardiac complexes are determined from cardiac complexes sensed from a patient population experiencing the cardiac state for which template cardiac complexes are developed. In one embodiment, the cardiac states for which template cardiac complexes can be developed include cardiac rhythms where the left chamber and the right chamber of the ventricles or atria differ by about 20 milliseconds or more, premature ventricular contractions, ischemia, predetermined or custom patterns or classes of complexes predetermined by a physician, arrhythmia, non-arrhythmia, ventricular or supraventricular tachycardia.

In one embodiment, as sensed cardiac complexes are sensed and classified, the microprocessor 616 determines the percentage of classified cardiac complexes for a plurality of sensed cardiac complexes. In one embodiment, the microprocessor 616 determines the percentage of cardiac complexes classified as arrhythmic complexes for a plurality of cardiac complexes sensed during an

arrhythmic episode. In one embodiment, once the percentage of classified cardiac complexes reaches a predetermined threshold for any one of the cardiac conditions or states programmed into the medical device system, the microprocessor 616 responds by providing signals to cardioversion/defibrillation output circuitry 652 to deliver either cardioversion or defibrillation therapy to the heart 506. Power to the cardiac defibrillator 500 is supplied by an electrochemical battery 656 that is housed within the cardiac defibrillator 500.

In addition to the catheter 502, it is possible to add additional electrodes, catheters and the accompanying required circuitry to the medical device system. For example, the cardiac defibrillator 500 can be equipped with electrodes on the surface of the housing 530 to sense surface like cardiac signals. In addition, the medical device system can further include an additional intracardiac catheter implanted in the supraventricular region of the heart. The additional intracardiac catheter includes at least one pacing electrode from which rate signals, or near field signals, from the atria are sensed and pacing pulses are delivered to pace the atrial chamber of the patient's heart. In an additional embodiment, the additional intracardiac catheter is implanted through the coronary sinus vein and down the great cardiac vein to position an electrode, such as a pacing electrode, adjacent to the left ventricular chamber of the heart.

In an alternative embodiment, the catheter 502 is implanted the supraventricular region of the heart for sensing or monitoring cardiac signals from the patient's atrial regions. In one embodiment, a pacing electrode at or adjacent the distal end of the intracardiac catheter is implanted in the coronary sinus vein to allow for rate signals to be sensed from the left atrium. In addition, far-field signals, or morphology signals, are sensed from the supraventricular region of the heart through the first defibrillation electrode and the second defibrillation electrode. In addition to implanting the catheter 502 in the supraventricular region of the heart, an additional atrial catheter can be implanted into the supraventricular region of the heart to allow for additional rate signals, or near-field signals, to be sensed along with the rate signals and morphology signals sensed with the catheter 502. Other intracardiac catheter arrangements and configurations known in the art are also possible and considered to be within the scope of the present system.

Referring now to Figure 7, there is shown an additional embodiment of the present subject matter. At step 700, a cardiac complex is detected during a tachycardia episode in the first signal and the second signal. In one embodiment, tachycardia episodes include, but are not limited to, ventricular  
5 tachycardias and supraventricular tachycardias. In one embodiment, the medical device system analyzes at least the cardiac complexes detected in the first signal to determine the occurrence of a tachycardia episode which will be classified by the present subject matter.

In one embodiment, the first signal and the second signal detect the  
10 occurrence of cardiac cycles through either a near-field sensing channel or a far-field sensing channel as previously discussed. Cardiac complexes sensed in the first signal and the second signals can include the QRS-wave, the R-wave and/or the P-wave of the cardiac complex. This list, however, is not to be taken in a limiting sense as it is recognized that other portions of the cardiac complex can  
15 also be sensed and used with the present subject matter.

As the cardiac complex is detected in the first signal and the second signal during the tachycardia episode, the first and second signal of the cardiac complex are windowed together so the cardiac complex in the first signal is positioned relative to the cardiac complex in the second signal. In other words, the  
20 first signal and the second signal for each sensed tachycardiac cardiac complex are positioned relative to each other according to their occurrence in time.

Figure 8 shows an example of a cardiac complex having been windowed at 800. In the example, 804 shows a tachycardiac cardiac complex monitored on a near-field sensing channel, while 808 shows the cardiac complex  
25 monitored on a far-field sensing channel.

After the cardiac complex has been windowed, the first and second signals of the cardiac complex are positioned or aligned relative to the first NSR representative complex and the second NSR representative complex. In one embodiment, the first and second NSR representative complexes are determined  
30 from a plurality of NSR cardiac complexes detected in the first signal and the second signal, respectively, using the same medical device system that is subsequently used to sense the cardiac complexes. In one embodiment, the first NSR representative complex and the second NSR representative complex are



derived by averaging cardiac complexes detected in the first and second signals for the plurality of NSR cardiac complexes sensed from the patient. In an alternative embodiment, the first NSR representative complex and the second NSR representative complex are derived by taking a median of cardiac  
5 complexes detected in the first and second signals for the plurality of NSR cardiac complexes sensed from the patient.

In addition, the first NSR representative complex and the second NSR representative complex can be updated, either manually or automatically, to reflect changes in a patient's cardiac condition or in the medical device system.  
10 For example, the first NSR representative complex and the second NSR representative complex could change due to the type of drug or dosage of drugs being delivered to the patient and the cardiac disease state of the patient. Therefore, the system can recompute the first NSR representative complex and the second NSR representative complex at regular intervals based either on the  
15 physician's judgement or on the implantable medical devices assessment of the template. Additionally, a safe-check algorithm can be used in conjunction with any automatic updating procedure to ensure that only normal sinus rhythm complexes are used in updating the template.

At 720, the cardiac complex detected in the first signal is aligned  
20 with the first NSR representative complex. In one embodiment, the cardiac complex in the first signal and the first NSR representative complex are aligned around a predetermined feature located in the cardiac complexes. In one embodiment, the predetermined feature includes a repeatably identifiable section, or portion, of the detected cardiac complex that is common to the cardiac  
25 complex detected in the first signal and the first NSR representative complex. In one embodiment, the repeatably identifiable complex section common to the cardiac complex detected in the first signal and the first NSR representative complex is a maximum deflection of the first signal. In one embodiment, the maximum deflection is along an R-wave sensed in the cardiac complex detected  
30 in the first signal and in the first NSR representative complex.

In an alternative embodiment, the repeatably identifiable complex section common to the cardiac complex detected in the first signal and the first NSR representative complex is a predetermined deviation of the first signal from

a baseline signal indicating a beginning of the cardiac complex and the first NSR representative complex. In an additional embodiment, the repeatably identifiable complex section common to the cardiac complex detected in the first signal and the first NSR representative complex is a return of the first signal to a baseline  
5 signal for each of the cardiac complex and the first NSR representative complex for a predetermined time period indicating an ending of the cardiac complex and the first NSR representative complex.

After the cardiac complex detected in the first signal has been aligned with the first NSR representative complex, the cardiac complex detected  
10 in the second signal is compared to the second NSR representative complex to determine whether the cardiac complex is an arrhythmic complex. One way of determining whether the cardiac complex is an arrhythmic complex is to compare the morphology of the second signal to the second NSR representative complex. In one embodiment, the second NSR representative complex has a second NSR  
15 morphology and the cardiac complex detected in the second signal has a second signal morphology. The second NSR morphology of the second NSR representative complex is then compared to the second signal morphology of the second signal to determine whether the cardiac complex is an arrhythmic complex. A variety of techniques exist for morphologic analysis of sensed  
20 cardiac complexes. In one embodiment, the morphology of the cardiac complex sensed in second signal and the morphology of the second NSR representative complex are compared using a correlation waveform analysis, as is known in the art. In addition to correlation waveform analysis, other morphology comparison methods or methods of classifying cardiac complexes sensed during an  
25 arrhythmic episode. Additional morphology analysis techniques include amplitude distribution analysis and spectral analysis. Other morphology analysis techniques are known and are considered to be within the scope of the present subject matter.

By initially aligning the cardiac complex detected in the first signal  
30 with the first NSR representative complex, the time the cardiac complex detected in the second signal and the second NSR representative complex occurred relative to the first signal with the first NSR representative complex become a

factor in determining what portion of the second NSR representative complex is compared to the cardiac complex in the second signal.

Figure 8 shows one embodiment of aligning the cardiac complex detected in the first signal with the first NSR representative complex. In 800  
5 there is shown a window containing a cardiac complex detected in a first signal 804 and a second signal 808. In one embodiment, the first signal 804 is a near-field signal of an R-wave, and the second signal 808 is a far-field signal of a QRS-cardiac complex. In 812 there is shown a window containing a first NSR representative complex 816 and a second NSR representative complex 820. In  
10 the present example, the first NSR representative complex 816 is a near-field signal of an R-wave, and the second NSR representative complex 820 is a far-field signal of a QRS-cardiac complex.

As previously discussed, the morphology analyzer circuit 648 locates the predetermined feature in the cardiac complex detected in the first  
15 signal 804 and in the first NSR representative complex 816. The signal feature comparison circuit 638 then aligns the predetermined feature in the cardiac complex monitored in the first signal 804 with the predetermined feature on the first NSR representative complex 816. In figure 8, the cardiac complex 800 and the first NSR representative complex 812 are aligned around a maximum  
20 deflection 824 of the cardiac complexes 804 and 816. The signal feature comparison circuit 638 then compares the cardiac complex monitored in the second signal 808 to the second NSR representative complex 820 to determine whether the cardiac complex is an arrhythmic complex. As previously  
discussed, because the predetermined feature in the cardiac complex monitored  
25 in the first signal 804 has been aligned with the predetermined feature on the first NSR representative complex 816, the time the second signal 808 occurs relative the first signal 804 and the time the second NSR representative complex 820 occurs relative the first NSR representative complex 816 can be used to accentuate morphological differences between the complexes. So in one  
30 embodiment, the QRS-cardiac complex 828 in the second signal 808 is morphologically compared to a region 832 along the second NSR representative complex 820. Alternatively, the QRS-cardiac complex 834 in the second NSR

representative complex 820 is morphologically compared to a region 836 along the second signal 808.

Figure 9 shows an alternative embodiment of aligning a cardiac complex sensed during a tachycardia episode with a normal sinus rhythm template cardiac complex. In 900 there is shown a window of a first NSR representative complex 904 and a second NSR representative complex 908. In the present example, the first NSR representative complex 904 is a far-field signal of a QRS-cardiac complex, and the second NSR representative complex 908 is a near-field signal of an R-wave cardiac complex. In 912 there is shown a window of a cardiac complex sensed during a tachycardia episode, where the first signal 916 is a far-field signal of a QRS-cardiac complex and the second signal 920 is a near-field signal of an R-wave cardiac complex.

In the present embodiment, the cardiac complex 912 and the representative NSR complex 900 are aligned around the beginning, or the start, of the cardiac complexes 904 and 916. After the representative NSR complex and the tachycardiac cardiac complex have been aligned, the morphology of the second signal 920 is compared to the morphology of the second NSR representative complex 908 to determine whether the cardiac complex is an arrhythmic complex. In one embodiment, the R-wave cardiac complex 924 in the second signal 920 is morphologically compared to a region 928 along the second NSR representative complex 908. In an alternative embodiment, the R-wave cardiac complex 930 in the second NSR representative complex 908 is morphologically compared to a region 932 along the second signal 920.

In one embodiment, the present subject matter can classify a variety of cardiac complexes, including VT-complexes, SVT-complexes and NSR-complexes. Other classifications for the tachycardiac cardiac complex are known and are considered within the scope of the present invention.

Figure 10 shows an additional embodiment of the present subject matter. At 1000, a first signal and a second signal representative of electrical cardiac activity are sensed from a patient. In one embodiment, each of the signals include cardiac complexes representative of cardiac cycles. At 1010, a plurality normal sinus rhythm (NSR) cardiac complexes are detected in the first signal and the second signal. In one embodiment, the medical device system

determines the first NSR representative complex from the plurality of NSR cardiac complexes detected in the first signal and determines the second NSR representative complex from the plurality of NSR cardiac complexes detected in the second signal. The first and second NSR representative complexes are then  
5 stored in the memory of the medical device system.

At 1020, cardiac complexes monitored in at least the first signal are analyzed by the medical device system to detect the onset of a tachycardia episode. If no tachycardia episode is detected, the system continues to sense cardiac signals and analyzes them for the occurrence of a tachycardia episode. In  
10 one embodiment, the occurrence of a tachycardia episode is based on the cardiac rate, where a tachycardia episode is declared when the cardiac rate exceeds a predetermined threshold. In one embodiment, the predetermined threshold is a cardiac rate of between 150 and 180 beats per minute. Other systems of determining the occurrence of a tachycardia episode are known and are  
15 considered to be within the scope of the present system.

When a tachycardia episode is detected the system then proceeds to 1030. At 1030, the first signal and the second signal are monitored for the occurrence of cardiac complexes. The detected cardiac complexes are analyzed, or processed, so that each cardiac complex is classified as either an arrhythmic  
20 complex or a non-arrhythmic complex. In processing each cardiac complex at 1030, the predetermined feature is located in the cardiac complex detected in the first signal and the first NSR representative complex. As previously discussed, the predetermined feature includes a repeatably identifiable portion of cardiac complexes.

25 At 1040, the predetermined feature on the cardiac complex sensed in the first signal is then aligned with the corresponding first feature found on the first NSR representative complex. In one embodiment, the predetermined feature on the first NSR representative complex has been previously located and stored in the memory of the medical device system. After the predetermined  
30 feature on both the cardiac complex sensed in the first signal and the first NSR representative complex have been aligned, the cardiac complex sensed in the second signal is compared to the second NSR representative complex at 1050. In one embodiment, the second NSR representative complex has a second NSR

morphology and the cardiac complex detected in the second signal has a second signal morphology, where the second NSR morphology is compared to the second signal morphology to determine whether the cardiac complex is an arrhythmic complex. Based on the comparison, the cardiac complex is classified  
5 as either an arrhythmic complex or as a non-arrhythmic complex at 1060.

After making a determination as to whether a cardiac complex is an arrhythmic complex or a non-arrhythmic complex, a percentage of arrhythmic complexes is determined at 1070. At 1080, the calculated percentage of arrhythmic complexes is compared to a predetermined percentage threshold. In  
10 one embodiment, therapy for treating the condition associated with the arrhythmic complexes being sensed is applied to the patient's heart at 1090 when the percentage of arrhythmic complexes exceeds the predetermined percentage threshold. If the percentage of arrhythmic complexes does not exceed the predetermined percentage threshold, the system returns to 1030. In one  
15 embodiment, the predetermined percentage threshold is a programmable value in the range of 40 to 60 percent, where a value of approximately 50 percent is an acceptable value.

Figure 11 shows an additional embodiment of the present subject matter. At 1100, a first signal and a second signal representative of electrical  
20 cardiac activity are sensed from a patient, where the first signal and the second signal each include at least a portion of a QRS-complex. At 1110, a plurality normal sinus rhythm (NSR) cardiac complexes are detected in the first signal and the second signal. The medical device system determines the first NSR representative complex from the at least a portion of the QRS-complex in each of  
25 the plurality of NSR cardiac complexes detected in the first signal and the second NSR representative complex from the at least a portion of the QRS-complex in each of the plurality of NSR cardiac complexes detected in the second signal. The first and second NSR representative complexes are then stored in the memory of the medical device system.

30 At 1120, cardiac complexes monitored in at least the first signal are analyzed by the medical device system to detect the onset of a tachycardia episode. If no tachycardia episode is detected, the system continues to sense cardiac signals and analyzes them for the occurrence of a tachycardia episode. In

one embodiment, the occurrence of a tachycardia episode is based on the ventricular cardiac rate, where a tachycardia episode is declared when the ventricular cardiac rate exceeds a predetermined threshold. In one embodiment, the predetermined threshold is a ventricular cardiac rate of between 150 and 180  
5 beats per minute. Other systems of determining the occurrence of a tachycardia episode are known and are considered to be within the scope of the present system.

When a tachycardia episode is detected the system then proceeds to 1130. At 1130, the first signal and the second signal are monitored for the  
10 occurrence of cardiac complexes. The detected cardiac complexes are analyzed, or processed, so that each cardiac complex is classified as either a ventricular tachycardia complex or a non-ventricular tachycardia complex. In processing each cardiac complex at 1130, the predetermined feature is located in the cardiac complex detected in the first signal and the first NSR representative complex.  
15 As previously discussed, the predetermined feature includes a repeatably identifiable portion of cardiac complexes.

At 1140, the predetermined feature on the cardiac complex sensed in the first signal is then aligned with the corresponding first feature found on the first NSR representative complex. In one embodiment, the predetermined  
20 feature on the first NSR representative complex has been previously located and stored in the memory of the medical device system. After the predetermined feature on both the cardiac complex sensed in the first signal and the first NSR representative complex have been aligned, the cardiac complex sensed in the second signal is compared to the second NSR representative complex at 1150.  
25 In one embodiment, the second NSR representative complex has a second NSR morphology and the cardiac complex detected in the second signal has a second signal morphology, where the second NSR morphology is compared to the second signal morphology to determine whether the cardiac complex is a ventricular tachycardia complex or a non-ventricular tachycardia complex.  
30 Based on the comparison, the cardiac complex is classified as either a ventricular tachycardia complex or a non-ventricular tachycardia complex at 1160.

After making a determination as to whether a cardiac complex is a ventricular tachycardia complex or a non-ventricular tachycardia complex, a

percentage of ventricular tachycardia complexes is determined at 1170. At 1180, the calculated percentage of ventricular tachycardia complexes is compared to a predetermined percentage threshold. In one embodiment, therapy for treating a ventricular tachycardia is applied to the patient's heart at 1190 when the percentage of ventricular tachycardia complexes exceeds the predetermined percentage threshold. If the percentage of ventricular tachycardia complexes does not exceed the predetermined percentage threshold, the system returns to 1130. In one embodiment, the predetermined percentage threshold is a programmable value in the range of 40 to 60 percent, where a value of approximately 50 percent is an acceptable value.

Figure 12 shows an additional embodiment of the present subject matter. At 1200, a first cardiac signal and a second cardiac signal representative of electrical cardiac activity are sensed and monitored from a patient. In one embodiment, the first cardiac signal and the second cardiac signal are monitored from a first cardiac region and a second cardiac region, respectively. At 1210, cardiac complexes are detected in the first cardiac signal and the second cardiac signal. As the cardiac complexes are sensed, template morphologies are developed for cardiac conditions exhibited by the patient. In one embodiment, as the patient experiences a cardiac condition (such as a ventricular tachycardia or supraventricular tachycardia) the cardiac complexes are recorded. In one embodiment, the system can then use the recorded cardiac complexes to develop a template morphology for the cardiac condition.

In one embodiment, the template morphology is comprised of a first template morphology and a second template morphology. In one embodiment, the first template morphology is derived from cardiac complexes monitored in the first cardiac signal sensed from approximately the first cardiac region and the second template morphology is derived from cardiac complexes monitored in the second cardiac signal sensed from approximately the second cardiac region. In an alternative embodiment, the first template morphology and the second template morphology for each cardiac condition of interest are developed through groups of patient data and programmed into the memory of the medical device system. The template cardiac complexes are then stored in the memory of the medical device system.



In one embodiment, the patient's cardiac complexes are monitored and analyzed by the medical device system. In one embodiment, the cardiac complexes are monitored for the onset of a tachycardia event. In an alternative embodiment, the cardiac complexes are monitored to detect the occurrence of a  
5 predetermined class or type of cardiac complex (e.g., PVCs, ischemic complexes). In one embodiment, to determine the occurrence of the predetermined class of cardiac complexes, the cardiac complexes sensed in the cardiac signals are morphologically compared to the template cardiac complexes.

For the present embodiment, the morphology of the cardiac  
10 complex in the first cardiac signal is compared to the first template morphology at 1220. At 1230, the morphology of the cardiac complex in the second cardiac signal is compared to the second template morphology of a cardiac condition template morphology. Based on the comparison, the sensed cardiac complexes are then classified as either belonging to or not belonging to one or more of the  
15 classes of cardiac complexes represented by the template cardiac complexes at 1240. After classifying each cardiac complex, the medical device system can retain the sensed cardiac complexes in memory. In addition, a percentage of the classified complexes is determined at 1070.

In an additional embodiment, a third cardiac signal containing the  
20 cardiac complex can be monitored. A third template morphology can be developed in the same manner as described for the first and second template morphologies. The morphology of the cardiac complex in the third cardiac signal is then compared to a third template morphology. So, the cardiac complex can be classified based on the comparison of the morphology of the cardiac  
25 complex in the first cardiac signal, the second cardiac signal and the third cardiac signal to the first template morphology, the second template morphology and the third template morphology.

## WHAT IS CLAIMED IS:

1. A system, comprising:
  - at least one lead adapted to sense signals;
  - a sensing system attached to the at least one lead, where the sensing
  - 5 system senses a first signal and a second signal;
  - a morphology analyzer circuit coupled to the sensing system,
  - wherein the morphology analyzer circuit locates a position of at least one
  - predetermined feature of the complex in the first signal and the second
  - signal and generates two or more scalar values as a function of the position
  - 10 of the at least one predetermined feature for each of the first signal and the
  - second signal; and
  - a template generator coupled to the morphology analyzer, wherein
  - the template generator circuit creates a vector from the two or more scalar
  - values generated by morphology analyzer circuit.
  - 15
2. The system of claim 1, where the template generator circuit determines a
- first representative complex and a second representative complex from a
- plurality complexes sensed during a normal rhythm.
- 20
3. The system of claim 2, where the morphology analyzer circuit locates the
- predetermined feature in the complex detected in the first signal and in the first
- representative complex, where the predetermined feature includes a repeatably
- identifiable complex section common to the complex detected in the first signal
- and the first representative complex.
- 25
4. The system of claim 3, including a signal feature comparison circuit
- coupled to the morphology analyzer circuit and the template generator circuit,
- where the signal feature comparison circuit aligns the predetermined feature in
- the complex monitored in the first signal with the predetermined feature on the
- 30 first representative complex and compares the complex monitored in the second
- signal to the second representative complex to determine whether the complex is
- a rapid complex.

5. The system of claim 4, where the morphology analyzer circuit locates the predetermined feature at a maximum deflection of the complex detected in the first signal and in the first representative complex.
- 5 6. The method of claim 5, where the maximum deflection is along a wave sensed in the complex detected in the first signal and in the first representative complex.
7. The system of claim 4, where the morphology analyzer circuit  
10 locates the predetermined feature at a beginning of the complex detected in the first signal and the first representative complex as indicated by a predetermined deviation of the first signal from a baseline signal.
8. The system of claim 4, where the morphology analyzer circuit  
15 locates the predetermined feature at an ending of the complex detected in the first signal and the first representative complex as indicated by a return of the first signal to a baseline signal for a predetermined time period.
9. The system of claim 4, where the sensing system includes a far-  
20 field sensing channel over which the first signal is monitored and a near-field sensing channel over which the second signal is monitored.
10. The system of claim 4, where the sensing system includes a near-  
field sensing channel over which the first signal is monitored and a far-  
25 field sensing channel over which the second signal is monitored.
11. The system of claim 4, where the second representative complex has a second morphology and the complex detected in the second signal has a second signal morphology, and the signal feature comparison circuit  
30 compares the second morphology to the second signal morphology to determine whether the complex is a rapid complex.

12. The system of claim 11, where the signal feature comparison circuit uses a correlation waveform analysis algorithm to compare the second morphology to the second signal morphology.
- 5 13. The system of claim 4, where the sensing system senses at least a portion of a complex in the first signal and the second signal, the template generator circuit determines the first representative complex and the second representative complex from the at least a portion of the complexes sensed during normal rhythm, and the signal feature comparison circuit  
10 compares the complex monitored in the second signal to the complex in the second representative complex to determine whether the complex is a rapid complex.
14. The system of claim 13, where the signal feature comparison  
15 circuit determines a percentage of rapid complexes for a plurality of complexes, and the control system determines therapy when the percentage of rapid complexes exceeds a predetermined percentage threshold.
15. The system of claim 14, where the predetermined percentage  
20 threshold is 50 percent.
16. The system of claim 1, including a signal feature comparison circuit coupled to the morphology analyzer circuit and the template generator circuit, wherein the signal feature comparison circuit compares  
25 the vector to one or more classification vectors to classify the complex.
17. The system of claim 16, wherein the at least one predetermined feature is a maximum deflection of the first signal and the second signal.
- 30 18. The system of claim 16, wherein the at least one predetermined feature is a predetermined deviation of the of the first signal and the second signal from a baseline signal indicating a beginning of the complex.

19. The system of claim 16, wherein the at least one predetermined feature is a return of the first signal and the second signal to a baseline signal for a predetermined time period indicating an ending of the complex.
- 5 20. The system of claim 16, wherein the scalar value is a time the at least one predetermined feature in the morphology of the complex occurred.
- 10 21. The system of claim 16, wherein the scalar value is a difference in time between the occurrence of a first predetermined feature and a second predetermined feature.
- 15 22. The system of claim 16, wherein the scalar value is a magnitude of the position of the at least one predetermined feature of the first signal and the second signal.
- 20 23. The system of claim 16, wherein the signal feature comparison circuit determines a similarity coefficient for each comparison of the vector to the one or more classification vectors, and classifies the complex as a predetermined condition when the similarity coefficient exceed a predetermined threshold.
- 25 24. The system of claim 16, wherein the signal feature comparison circuit aligns the vector with each of the one or more classification vectors prior to comparing the vectors, where the vector includes element positions occupied by the scalar values, and each of the one or more classification vectors includes an equal number of element positions as the element positions of the vector, wherein the element positions of the one or more classification vectors are occupied by scalar values representing the predetermined condition, and wherein the vector is aligned with a classification vector of the one or more classification vectors by adjusting each scalar value of the vector so one of the element positions of the vector
- 30

equals a scalar value in a corresponding element position in a classification vector.

25. A method, comprising:
- 5        monitoring two or more signals;  
      detecting a complex in each of the two or more signals;  
      comparing a morphology of the complex in each of the two or more  
signals to the morphology of a template complex; and  
      classifying the complex based on the comparison of the  
10       morphology of the complex in each of the two or more signals to the  
morphology of the template complex.
26.        The method of claim 25, wherein monitoring two or more signals  
includes monitoring a first signal and a second signal;
- 15        analyzing the at least the first signal to detect an episode;  
      when the episode is detected, detecting the complex in the first  
signal and the second signal;  
      wherein comparing the morphology includes locating a  
predetermined feature in the complex detected in the first signal and a first  
20       representative complex, wherein the predetermined feature includes a  
repeatably identifiable complex section common to the complex detected  
in the first signal and the first representative complex;  
      aligning the predetermined feature in the complex detected in the  
first signal and the first representative complex; and
- 25        wherein classifying the complex based on the comparison includes  
comparing the complex detected in the second signal to a second  
representative complex to determine whether the complex is a rapid  
complex.
- 30 27.        The method of claim 26, including detecting a plurality of normal  
complexes in the first signal and the second signal;  
      determining the first representative complex from the plurality of  
normal complexes detected in the first signal; and

determining the second representative complex from the plurality of normal cardiac complexes detected in the second signal.

28.           The method of claim 26, where the repeatably identifiable complex  
5           section common to the complex detected in the first signal and the first  
representative complex is a maximum deflection of the first signal.
29.           The method of claim 28, where the maximum deflection is along a  
10           wave sensed in the complex detected in the first signal and in the first  
representative complex.
30.           The method of claim 26, where the repeatably identifiable complex  
15           section common to the complex detected in the first signal and the first  
representative complex is a predetermined deviation of the first signal from  
a baseline signal indicating a beginning of the complex and the first  
representative complex.
31.           The method of claim 26, where the repeatably identifiable complex  
20           section common to the complex detected in the first signal and the first  
representative complex is a return of the first signal to a baseline signal for  
each of the complex and the first representative complex for a  
predetermined time period indicating an ending of the complex and the  
first representative complex.
- 25 32.           The method of claim 26, where the second representative complex  
has a second morphology and the complex detected in the second signal  
has a second signal morphology, and comparing the complex detected in  
the second signal to the second representative complex includes comparing  
the second morphology to the second signal morphology to determine  
30           whether the complex is a rapid complex.

33. The method of claim 32, where comparing the second morphology to the second signal morphology includes utilizing a correlation waveform analysis algorithm.
- 5 34. The method of claim 26, where sensing the first signal includes sensing electrical activity through a far-field sensing channel, and sensing the second signal includes sensing electrical activity through a near-field sensing channel.
- 10 35. The method of claim 26, where sensing the first signal includes sensing electrical activity through a near-field sensing channel, and sensing the second signal includes sensing electrical activity through a far-field sensing channel.
- 15 36. The method of claim 26, including detecting at least a portion of a complex in each of the plurality of normal complexes;  
determining the first representative complex from the at least a portion of the complex in each of the plurality of normal complexes detected in the first signal;  
20 determining the second representative complex from the at least a portion of the complex in each of the plurality of normal complexes detected in the second signal;  
comparing a second morphology to the second signal morphology to determine whether the complex is a fast complex;  
25 determining a percentage of the fast complex in a plurality of complexes sensed during the episode; and  
determining therapy when the percentage of the fast complexes exceeds a predetermined percentage threshold.
- 30 37. The method of claim 36, where the predetermined percentage threshold is 50 percent.



38. The method of claim 25, wherein comparing comprises locating at least one predetermined feature in the complex for each of the two or more signals, wherein the at least one predetermined feature includes a repeatably identifiable complex portion;
- 5 generating a scalar value as a function of a position of the at least one predetermined feature for each of the two or more signals;
- using the scalar values to create a vector, where the vector represents the complex; and
- classifying comprises comparing the vector to one or more
- 10 classification vectors, where each of the one or more classification vectors represents a predetermined condition;
- determining a similarity coefficient from each comparison of the vector and the one or more classification vectors; and
- classifying the complex as the predetermined condition when the
- 15 complex similarity coefficient exceed a predetermined threshold.
39. The method of claim 38, where detecting the complex includes isolating the complex in an analysis window.
- 20 40. The method of claim 38, where the at least one predetermined feature in the complex is a maximum deflection of the two or more signals.
41. The method of claim 38, where the at least one predetermined feature in the complex is a predetermined deviation of the two or more
- 25 signals from a baseline signal indicating a beginning of the complex.
42. The method of claim 38, where the at least one predetermined feature in the complex is a return of the two or more signal to a baseline signal for a predetermined time period indicating an ending of the
- 30 complex.
43. The method of claim 38, where the scalar value is a time the at least one predetermined feature of the complex occurred.

44. The method of claim 38, where the scalar value is a difference in time between the occurrence of two of the at least one predetermined feature.
- 5 45. The method of claim 28, where the scalar value is a magnitude of the position of the at least one predetermined feature for each of the two or more signals.
- 10 46. The method of claim 28, where determining a similarity coefficient comprises determining a mean square error value from each comparison of the vector and the one or more classification vectors.
- 15 47. The method of claim 28, including aligning the vector with each of the one or more classification vectors prior to comparing the vector, where the vector includes element positions occupied by the scalar values, and each of the one or more classification vectors includes an equal number of element positions as the element positions of the vector, wherein the element positions of the one or more classification vectors are occupied by scalar values representing the predetermined condition, and wherein the vector is aligned with a classification vector of the one or more classification vectors by adjusting each scalar value of the vector so one of the element positions of the vector equals a scalar value in a corresponding element position in a classification vector.
- 20 48. The method of claim 25, wherein monitoring two or more signals includes monitoring a first signal and a second signal;  
detecting the complex includes detecting the complex in each of the first signal and the second signal;  
comparing the morphology includes comparing the morphology of the complex in the first signal to a first template morphology and  
30 comparing the morphology of the complex in the second signal to a second template morphology; and

classifying the complex includes classifying the complex based on the comparison of the morphology of the complex in the first signal and the second signal to the first template morphology and the second template morphology.

5

49. The method of claim 48, where monitoring the first signal and the second signal comprises monitoring the first signal from a first region and the second signal from a second region.

10 50. The method of claim 48, including deriving the first template morphology from complexes sensed from approximately the first region.

51. The method of claim 48, including deriving the second template morphology from complexes sensed from approximately the second  
15 region.

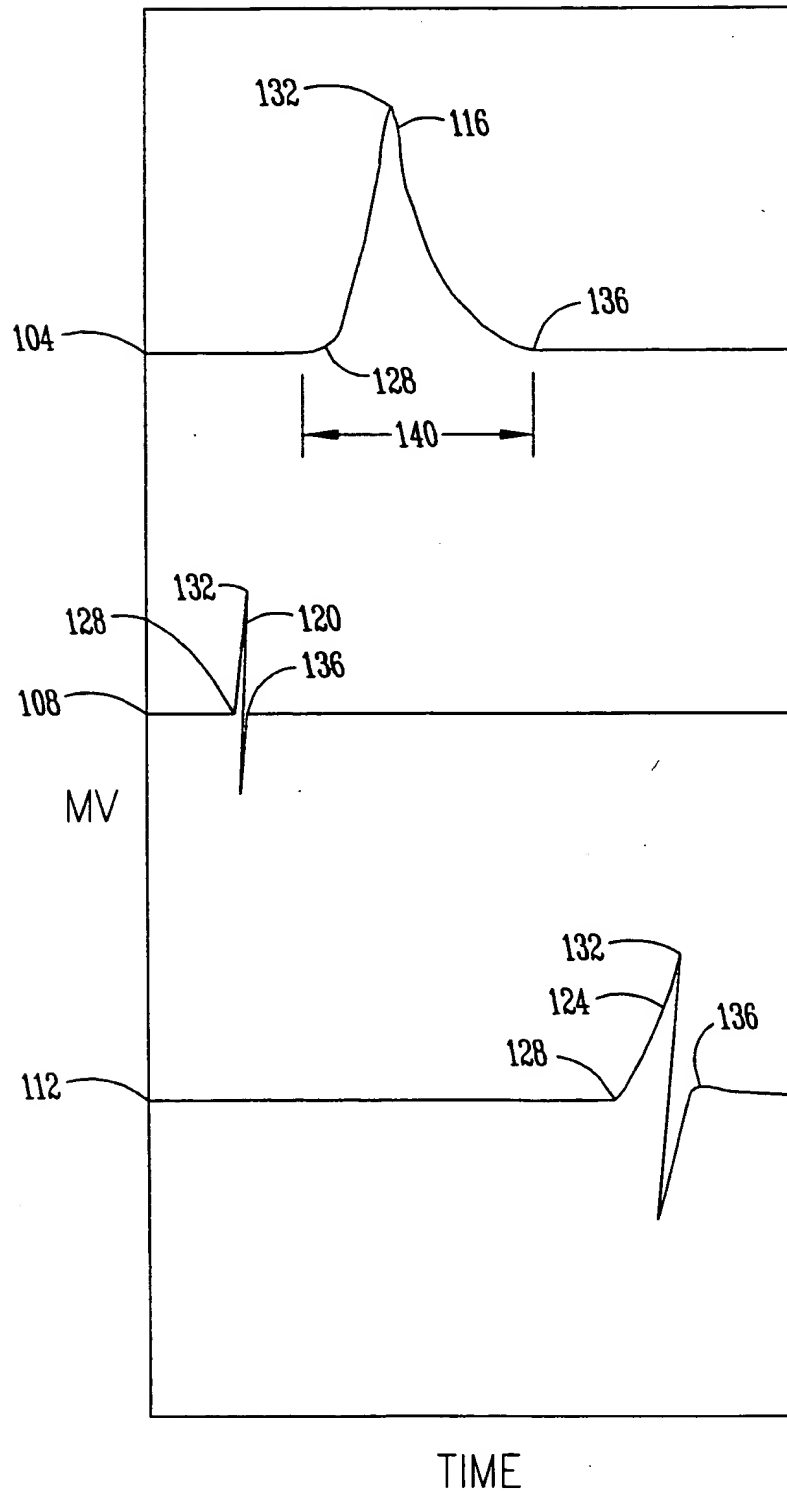
52. The method of claim 48, including:  
monitoring a third signal;  
detecting the complex in the third signal;  
20 comparing the morphology of the complex in the third signal to a third template morphology; and  
classifying the complex based on the comparison of the morphology of the complex in the first signal, the second signal and the third signal to the first template morphology, the second template  
25 morphology and the third template morphology.

53. The method of claim 52, where monitoring the third signal comprises monitoring the third signal from a third region.

30 54. The method of claim 53, including deriving the third template morphology from complexes sensed from approximately the third region.

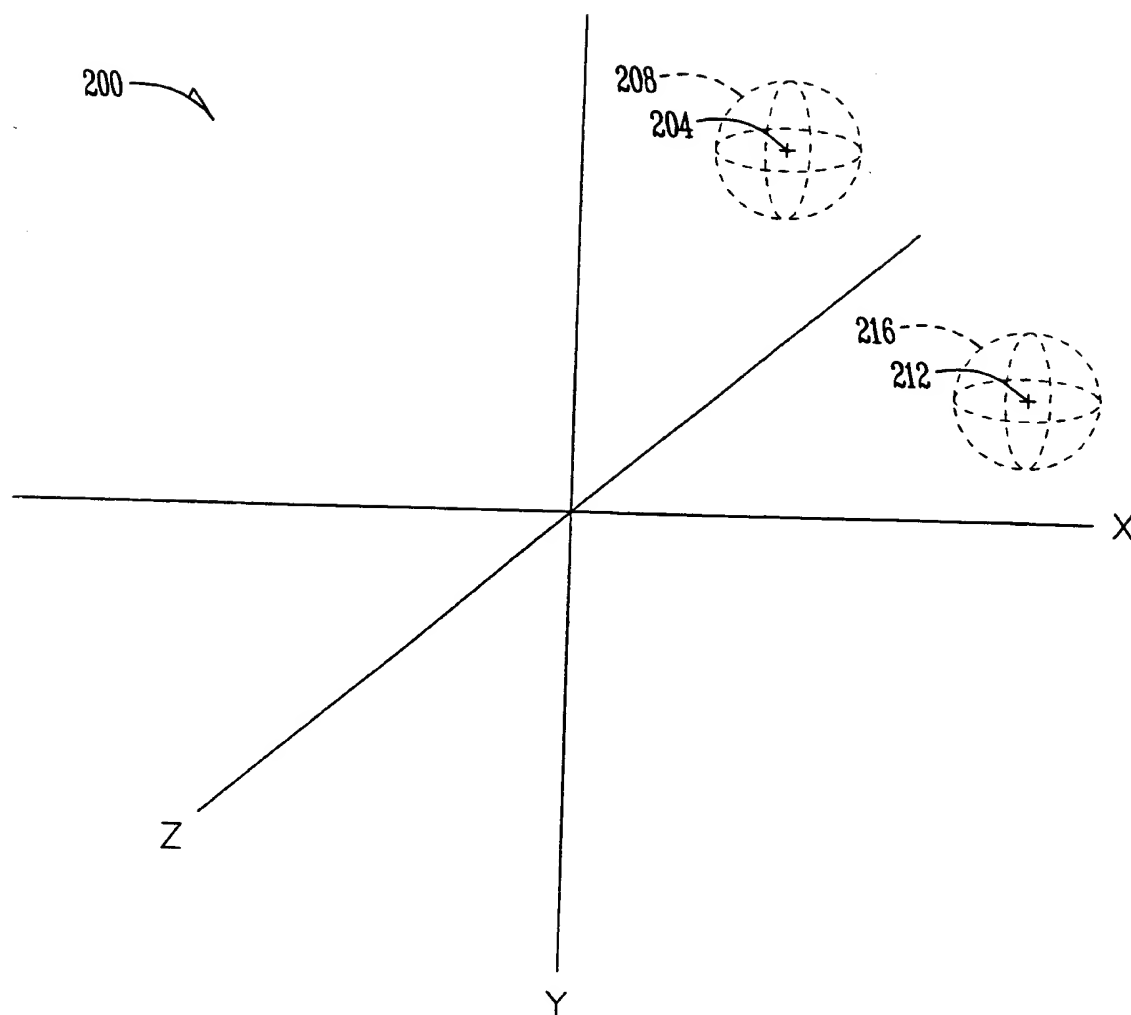
55. The system or method of any of the forgoing claims, wherein:  
two or more signals are two or more cardiac signals representative of  
electrical cardiac activity;  
the complex is a cardiac complex;  
5 the template complex is a template cardiac complex;  
the episode is a tachycardia episode;  
the first representative complex is a first normal sinus rhythm  
representative complex;  
the second representative complex is a second normal sinus rhythm  
10 representative complex;  
the rapid complex is an arrhythmic cardiac complex;  
the normal rhythm is a normal sinus rhythm;  
the normal complexes are normal sinus rhythm complexes;  
the second morphology is a second normal sinus rhythm morphology;  
15 the portion of the complex is a portion of a QRS-complex;  
the plurality of complexes is a plurality of normal sinus rhythm cardiac  
complexes;  
the fast complex is a ventricular tachycardia complex;  
the first region is a first cardiac region;  
20 the second region is a second cardiac region;  
the third signal is a third cardiac signal; and  
the third region is a third cardiac region.

100

*Fig. 1*

SUBSTITUTE SHEET (RULE 26)

2/11

*Fig. 2*

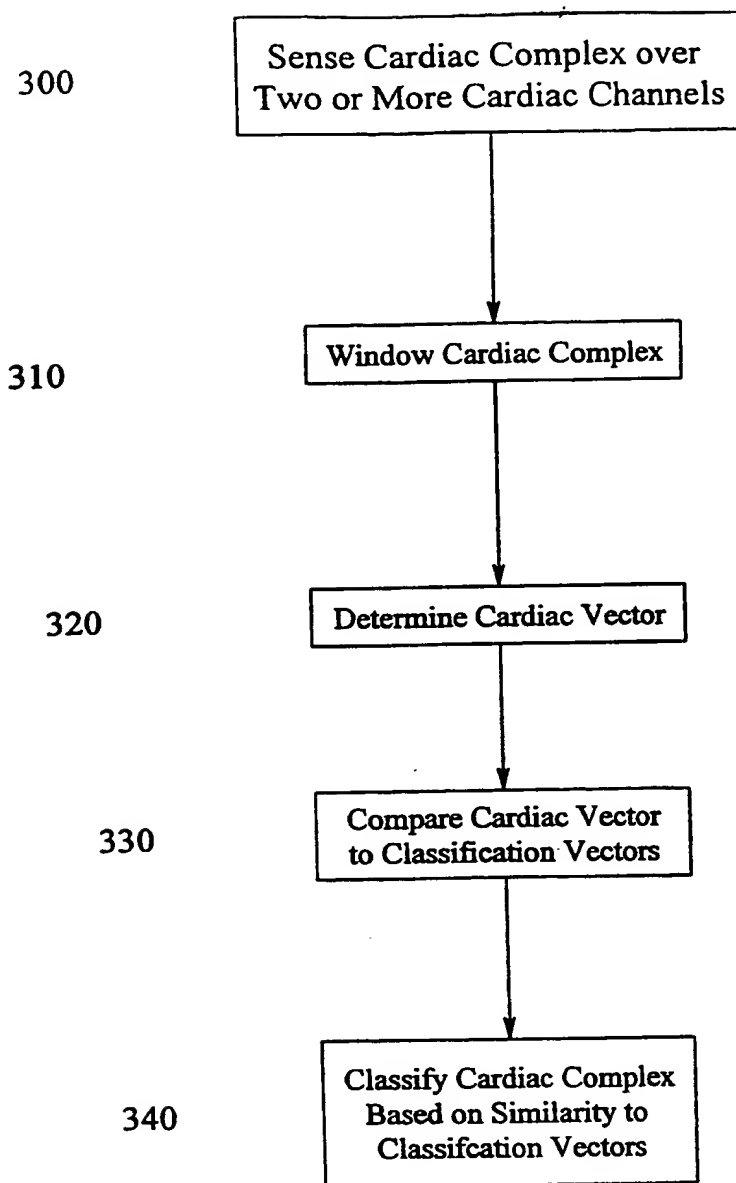
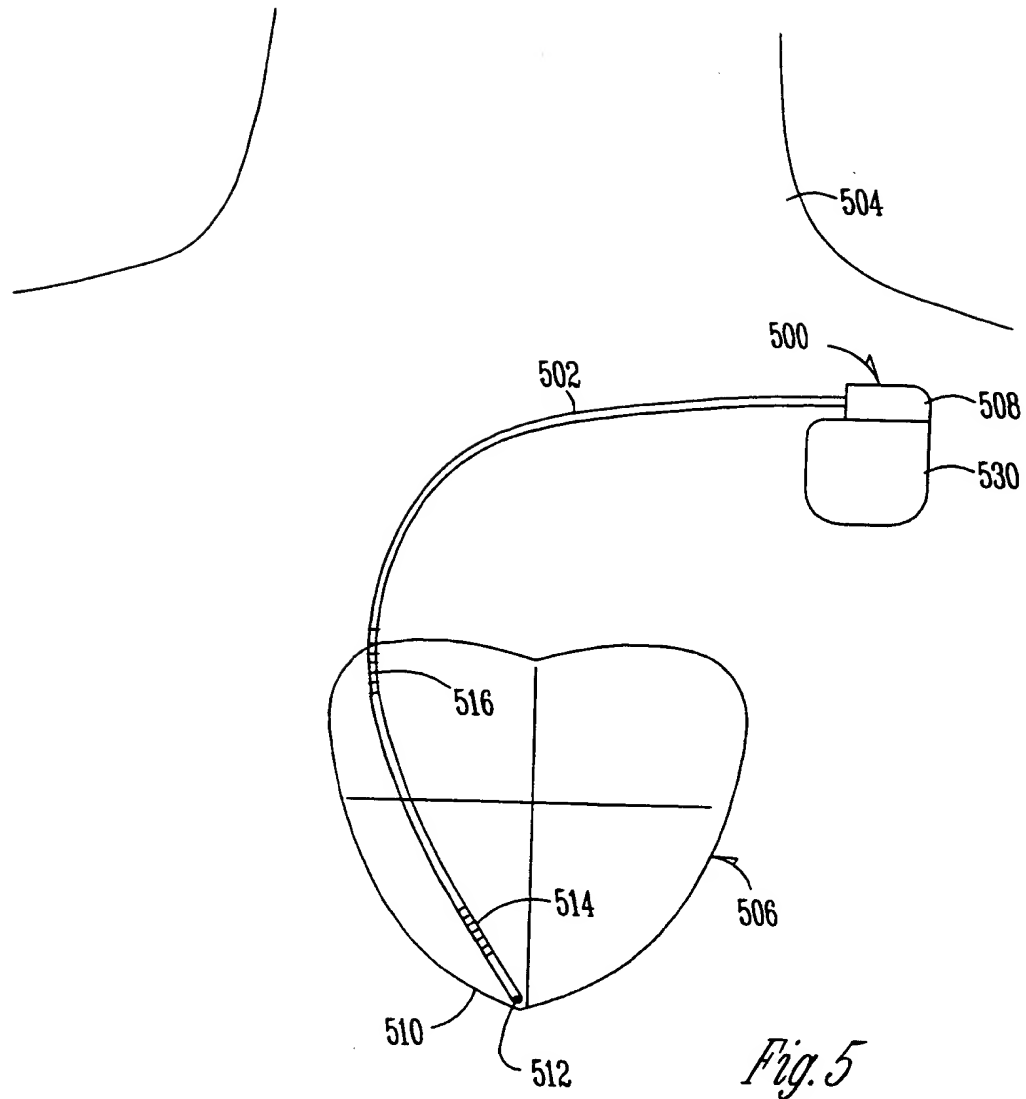


FIGURE 3





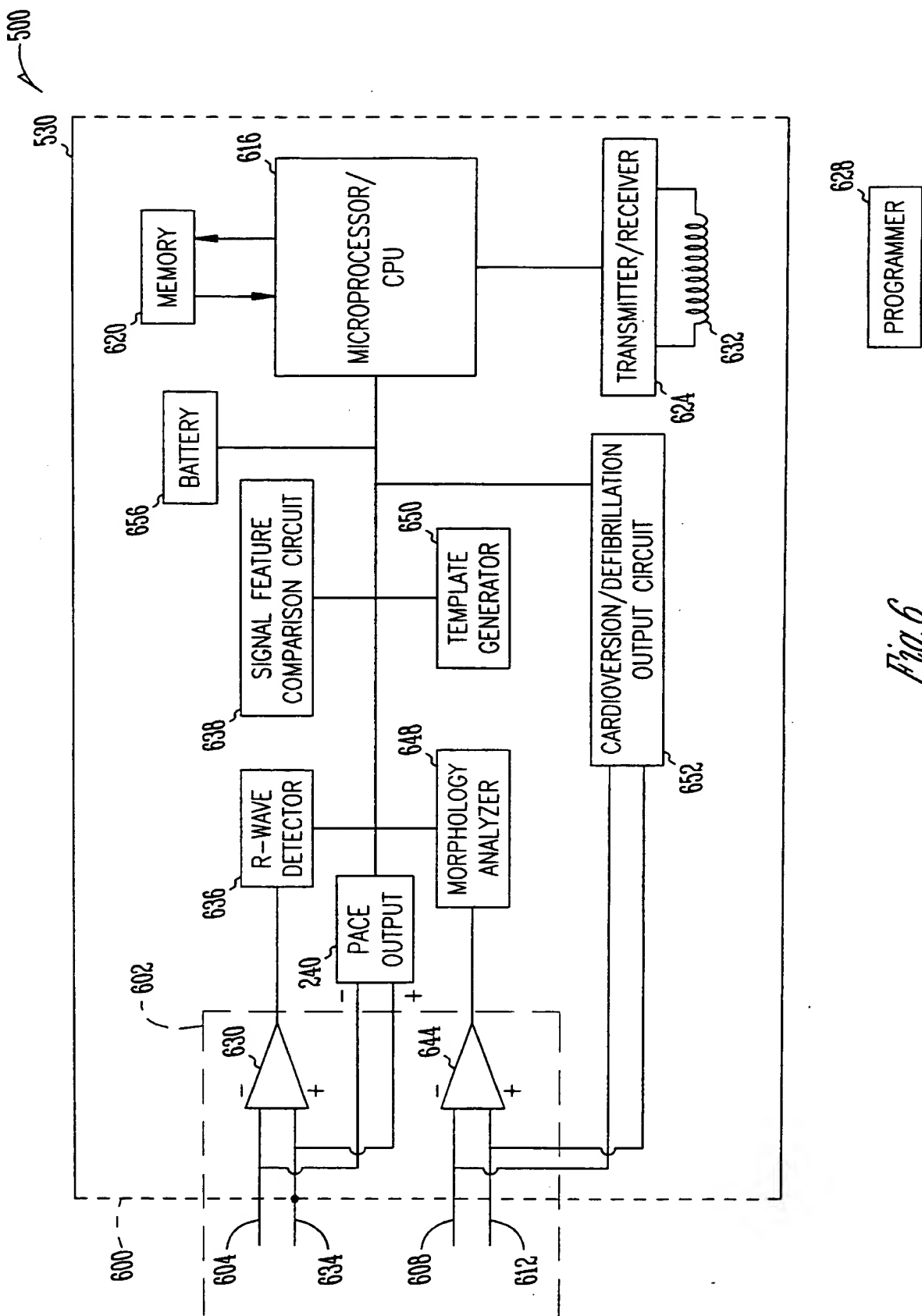
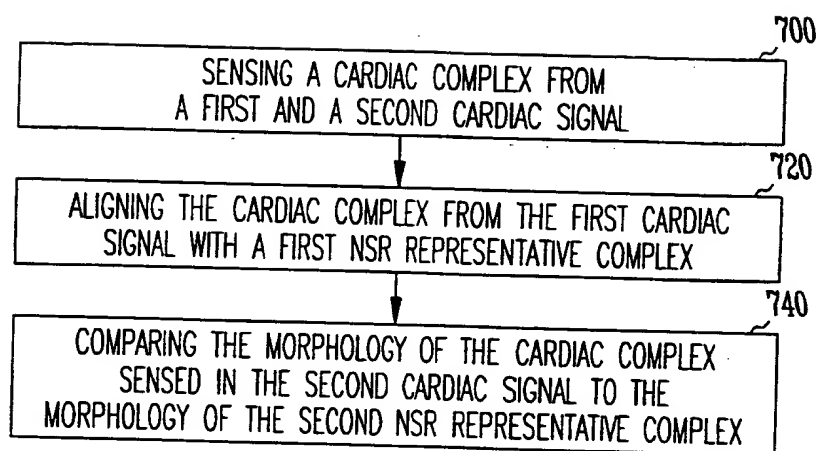
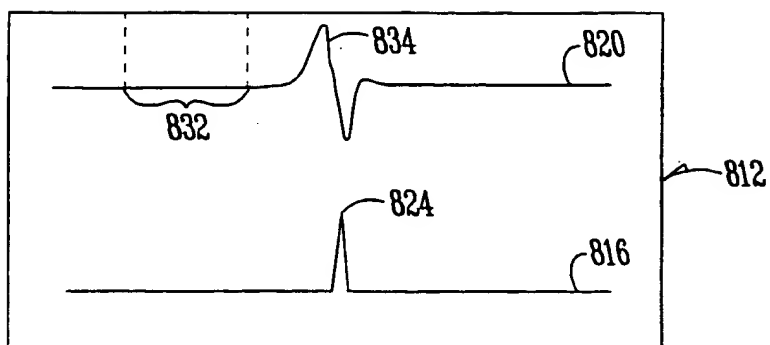
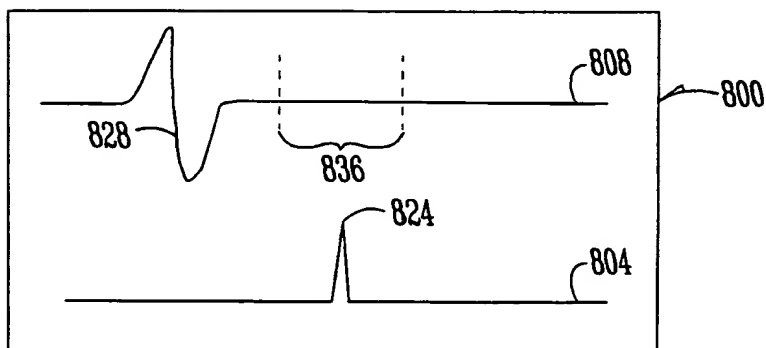


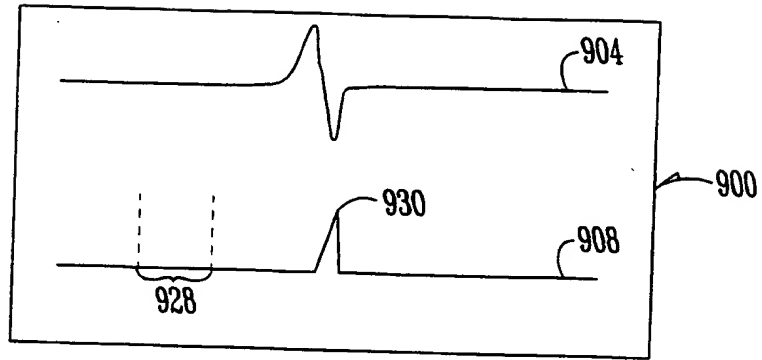
Fig. 6

6/11

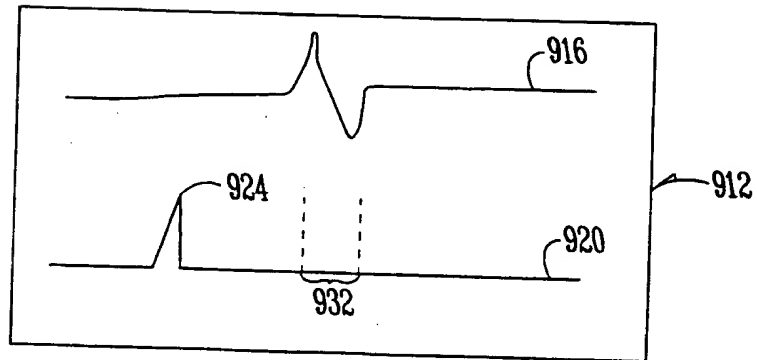
*Fig. 7*

7/11

*Fig. 8A**Fig. 8B*



*Fig. 9A*



*Fig. 9B*

9/11

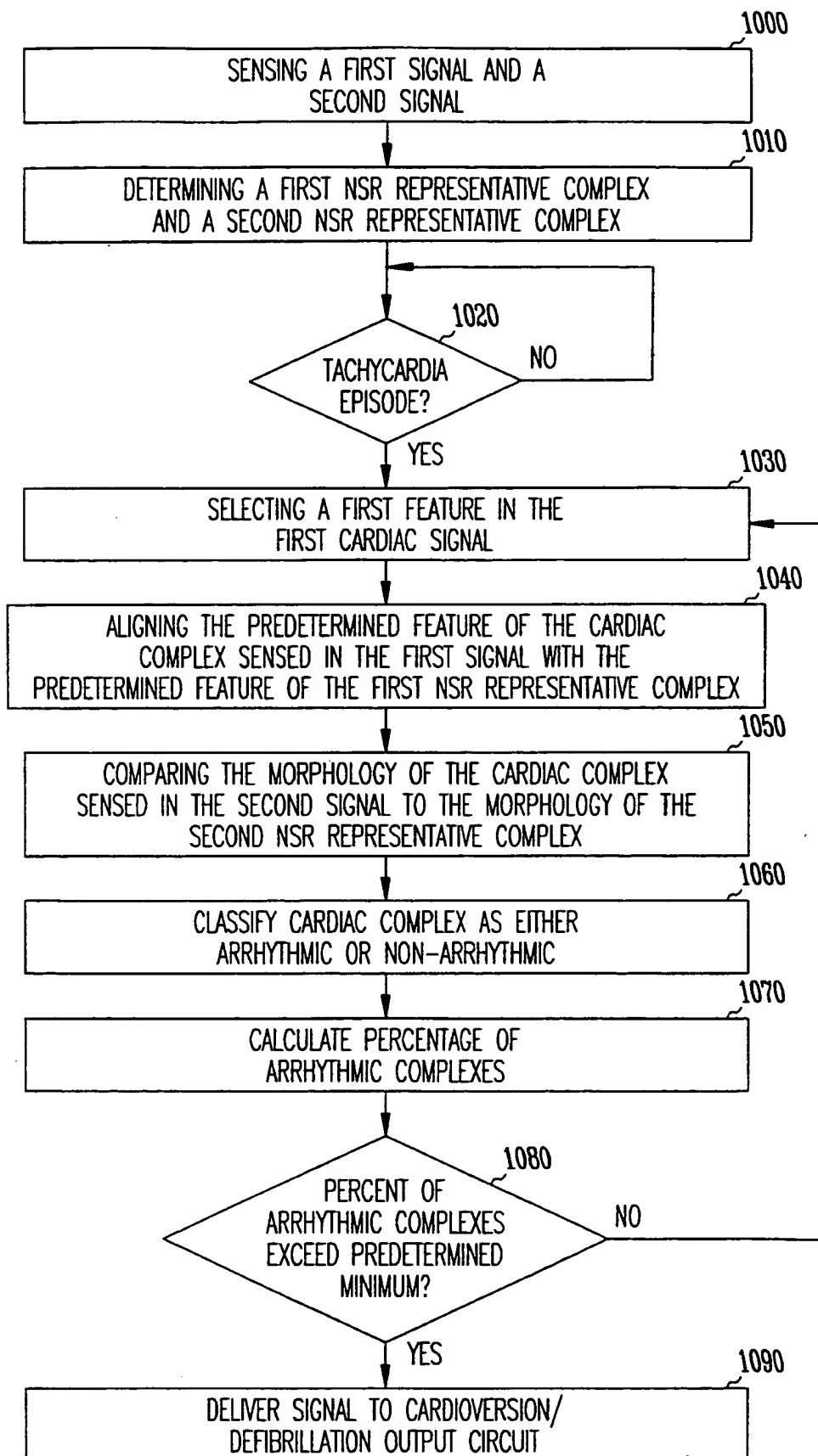


Fig. 10

10/11

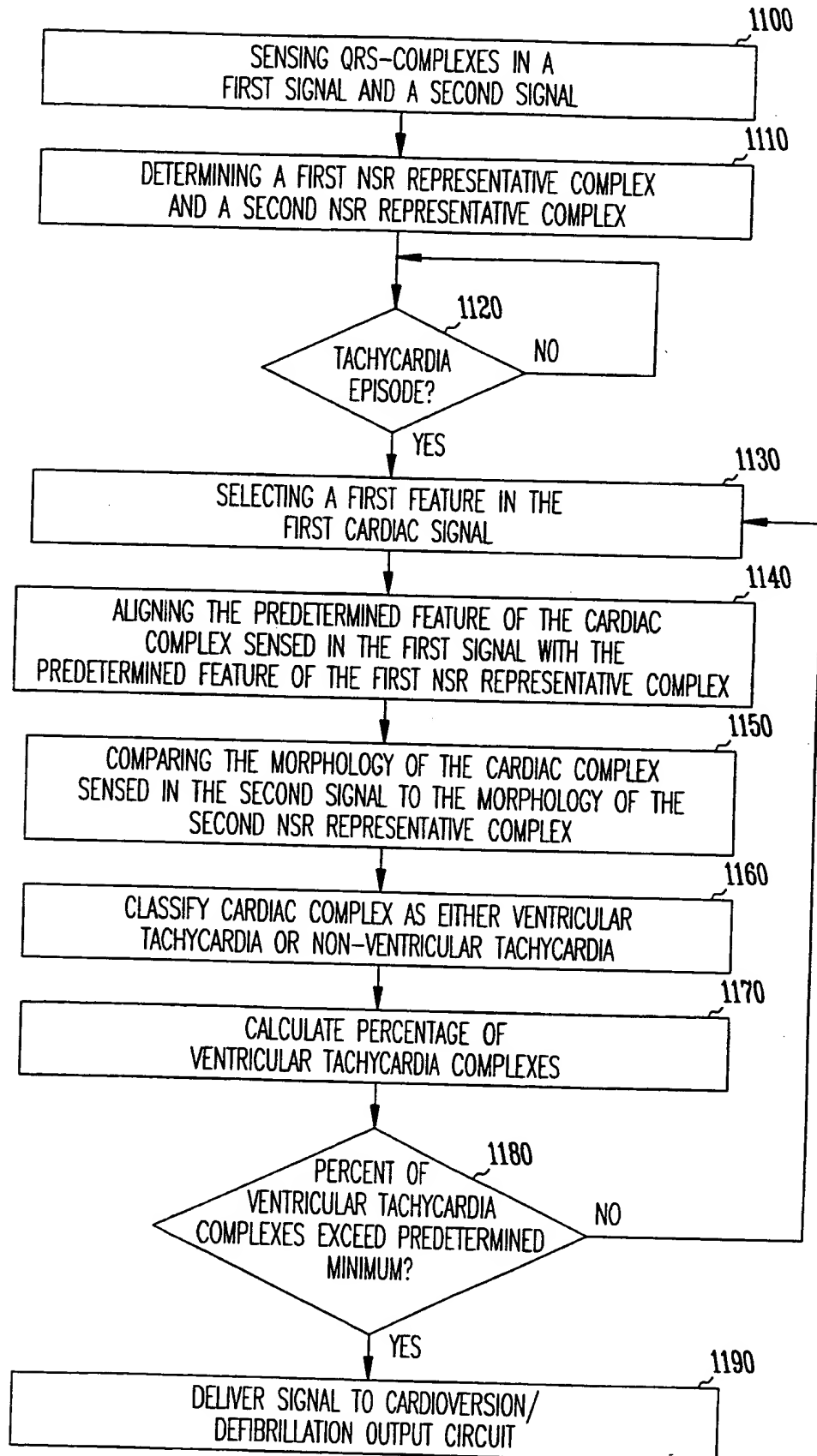
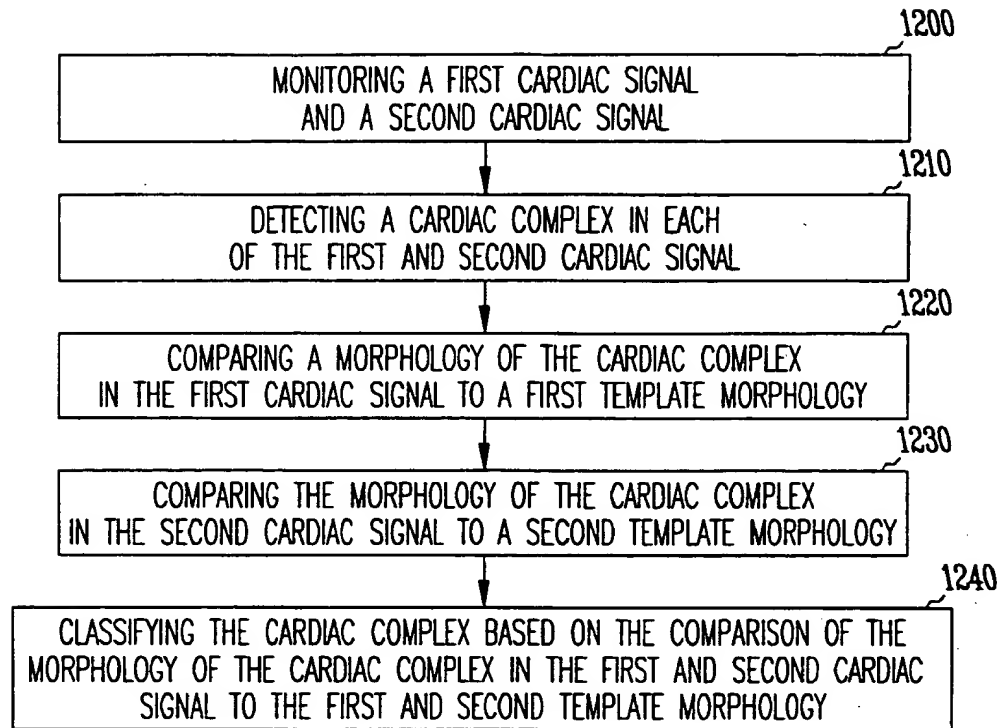


Fig. 11

11/11

*Fig. 12*

# INTERNATIONAL SEARCH REPORT

International Application No  
PCT/US 00/03604

**A. CLASSIFICATION OF SUBJECT MATTER**  
IPC 7 A61N1/37 A61N1/362

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)  
IPC 7 A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)  
EPO-Internal, WPI Data

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	US 5 271 411 A (KAPLAN DANIEL T ET AL) 21 December 1993 (1993-12-21) the whole document	1-4, 16 5-15, 17-24, 55
X A	US 5 193 550 A (DUFFIN EDWIN G) 16 March 1993 (1993-03-16) column 3-15; figures	1-4, 16 5-15, 17-24, 55
X A	US 5 645 070 A (TURCOTT ROBERT) 8 July 1997 (1997-07-08) column 4-6; figures	1-4, 16 5-15, 17-24, 55
X A	US 5 712 801 A (TURCOTT ROBERT) 27 January 1998 (1998-01-27) the whole document	1 2-24, 55
-/--		

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

\* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "8" document member of the same patent family

Date of the actual completion of the international search

21 July 2000

Date of mailing of the international search report

28/07/2000

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax: (+31-70) 340-3016

Authorized officer

Allen, E

Form PCT/ISA/210 (second sheet) (July 1992)



# INTERNATIONAL SEARCH REPORT

national Application No  
PCT/US 00/03604

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	US 5 311 874 A (LANG DOUGLAS ET AL) 17 May 1994 (1994-05-17) the whole document	1-4, 16 5-15, 17-24, 55
X A	EP 0 711 531 A (KARLSSON PER ;LUNDAHL GUNILLA (SE); UBBY JOHAN (SE); OLJEMARK MICH) 15 May 1996 (1996-05-15) page 2-7; figures	1-4, 16 5-15, 17-24, 55
X A	US 5 792 065 A (XUE QIUZHEN ET AL) 11 August 1998 (1998-08-11) column 3-7	1-4, 16 5-15, 17-24, 55

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No  
PCT/US 00/03604

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5271411 A	21-12-1993	JP 6022915 A	01-02-1994
US 5193550 A	16-03-1993	AU 651649 B	28-07-1994
		AU 9112191 A	25-06-1992
		CA 2095014 A	31-05-1992
		DE 69106531 D	16-02-1995
		DE 69106531 T	11-05-1995
		EP 0559780 A	15-09-1993
		WO 9209331 A	11-06-1992
US 5645070 A	08-07-1997	NONE	
US 5712801 A	27-01-1998	NONE	
US 5311874 A	17-05-1994	AU 1488095 A	25-05-1995
		AU 3862893 A	25-11-1993
		CA 2096454 A,C	19-11-1993
		EP 0570896 A	24-11-1993
		JP 6090915 A	05-04-1994
EP 0711531 A	15-05-1996	US 5520191 A	28-05-1996
		JP 8182660 A	16-07-1996
		US 6038469 A	14-03-2000
		US 5819741 A	13-10-1998
US 5792065 A	11-08-1998	NONE	

**This Page is Inserted by IFW Indexing and Scanning  
Operations and is not part of the Official Record**

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ **BLACK BORDERS**
- ☐ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- ☐ **FADED TEXT OR DRAWING**
- ☐ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- ☐ **SKEWED/SLANTED IMAGES**
- ☐ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- ☐ **GRAY SCALE DOCUMENTS**
- ☐ **LINES OR MARKS ON ORIGINAL DOCUMENT**
- ☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- ☐ **OTHER:** \_\_\_\_\_

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.**

**This Page Blank (uspto)**